Spinal manipulative therapy for chronic low-back pain (Review)

Rubinstein SM, van Middelkoop M, Assendelft WJJ, de Boer MR, van Tulder MW

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[Intervention Review]

Spinal manipulative therapy for chronic low-back pain

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ABSTRACT

Background

Many therapies exist for the treatment of low-back pain including spinal manipulative therapy (SMT), which is a worldwide, extensively practiced intervention.

Objectives

To assess the effects of SMT for chronic low-back pain.

Search methods

An updated search was conducted by an experienced librarian to June 2009 for randomised controlled trials (RCTs) in CENTRAL (*The Cochrane Library* 2009, issue 2), MEDLINE, EMBASE, CINAHL, PEDro, and the Index to Chiropractic Literature.

Selection criteria

RCTs which examined the effectiveness of spinal manipulation or mobilisation in adults with chronic low-back pain were included. No restrictions were placed on the setting or type of pain; studies which exclusively examined sciatica were excluded. The primary outcomes were pain, functional status and perceived recovery. Secondary outcomes were return-to-work and quality of life.

Data collection and analysis

Two review authors independently conducted the study selection, risk of bias assessment and data extraction. GRADE was used to assess the quality of the evidence. Sensitivity analyses and investigation of heterogeneity were performed, where possible, for the meta-analyses.

Main results

We included 26 RCTs (total participants = 6070), nine of which had a low risk of bias. Approximately two-thirds of the included studies (N = 18) were not evaluated in the previous review. In general, there is high quality evidence that SMT has a small, statistically significant but not clinically relevant, short-term effect on pain relief (MD: -4.16, 95% CI -6.97 to -1.36) and functional status (SMD: -0.22, 95% CI -0.36 to -0.07) compared to other interventions. Sensitivity analyses confirmed the robustness of these findings. There is varying quality of evidence (ranging from low to high) that SMT has a statistically significant short-term effect on pain relief and functional status when added to another intervention. There is very low quality evidence that SMT is not statistically significantly more effective than inert interventions or sham SMT for short-term pain relief or functional status. Data were particularly sparse for recovery, return-to-work, quality of life, and costs of care. No serious complications were observed with SMT.

Authors' conclusions

High quality evidence suggests that there is no clinically relevant difference between SMT and other interventions for reducing pain and improving function in patients with chronic low-back pain. Determining cost-effectiveness of care has high priority. Further research is likely to have an important impact on our confidence in the estimate of effect in relation to inert interventions and sham SMT, and data related to recovery.

PLAIN LANGUAGE SUMMARY

Spinal manipulative therapy for chronic low-back pain

Spinal manipulative therapy (SMT) is an intervention that is widely practiced by a variety of health care professionals worldwide. The effectiveness of this form of therapy for the management of chronic low-back pain has come under dispute.

Low-back pain is a common and disabling disorder, which represents a great burden to the individual and society. It often results in reduced quality of life, time lost from work and substantial medical expense. In this review, chronic low-back pain is defined as low-back pain lasting longer than 12 weeks. For this review, we only included cases of low-back pain that were not caused by known underlying conditions, for example, infection, tumour, or fracture. We also included patients whose pain was predominantly in the lower back, but may also have radiated (spread) into the buttocks and legs.

SMT is known as a "hands-on" treatment of the spine, which includes both manipulation and mobilisation. In manual mobilisations, the therapist moves the patient's spine within their range of motion. They use slow, passive movements, starting with a small range and gradually increasing to a larger range of motion. Manipulation is a passive technique where the therapist applies a specifically directed manual impulse, or thrust, to a joint, at or near the end of the passive (or physiological) range of motion. This is often accompanied by an audible 'crack'.

In this updated review, we identified 26 randomised controlled trials (represented by 6070 participants) that assessed the effects of SMT in patients with chronic low-back pain. Treatment was delivered by a variety of practitioners, including chiropractors, manual therapists and osteopaths. Only nine trials were considered to have a low risk of bias. In other words, results in which we could put some confidence.

The results of this review demonstrate that SMT appears to be as effective as other common therapies prescribed for chronic low-back pain, such as, exercise therapy, standard medical care or physiotherapy. However, it is less clear how it compares to inert interventions or sham (placebo) treatment because there are only a few studies, typically with a high risk of bias, which investigated these factors. Approximately two-thirds of the studies had a high risk of bias, which means we cannot be completely confident with their results. Furthermore, no serious complications were observed with SMT.

In summary, SMT appears to be no better or worse than other existing therapies for patients with chronic low-back pain.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Spinal manipulative therapy compared to inert interventions for chronic low-back pain

Patient or population: patients with chronic low-back pain
Settings: Rather diverse
Intervention: spinal manipulative therapy
Comparison: inert interventions

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	inert interventions	spinal manipulative therapy				
Pain VAS. Scale from 0-100 (worse pain). Follow-up: 1 month	The mean pain in the control groups was **27 points**	The mean Pain in the intervention groups was **6.00 lower** (15.82 lower to 3.82 higher)		72 (1 study)	⊕○○○ **very low**[1,2,3]	
Pain VAS. Scale from 0-100 (worse pain). Follow-up: 3 months	The mean pain in the control groups was **6 points**	The mean Pain in the intervention groups was **7.00 higher** (3.58 lower to 17.58 higher)		70 (1 study)	⊕○○○ **very low**[1,2,3]	
Recovery at 1 month	**Study population**		**RR 1.03** (0.49 to 2.19)	72 (1 study)	⊕○○○ **very low**[1,2,4]	
	273 per 1000	**281 per 1000** (134 to 598)				
	Medium risk population					

Recovery at 3 months	**Study population**		**RR 0.96** (0.56 to 1.65)	70 (1 study)	⊕○○○ **very low**[1,2,4]
	438 per 1000	**420 per 1000** (245 to 723)			
	Medium risk population				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] High risk of bias
[2] Less than 400 subjects, total.
[3] Effect includes the possibility of better or worse pain relief with SMT.
[4] Effect includes the possibility of better or worse chance of recovery with SMT.

BACKGROUND

Low-back pain is a common and disabling disorder in western society, which represents a great financial burden in the form of direct costs resulting from loss of work and medical expenses, as well as indirect costs (Dagenais 2008). Therefore, adequate treatment of low-back pain is an important issue for patients, treating clinicians, and healthcare policy makers. Spinal manipulative therapy (SMT) is widely used for acute and chronic low-back pain, which has been examined in many randomised controlled trials (RCTs). These trials have been summarized in numerous recent systematic reviews (Brønfort 2004a; Brown 2007; Brox 1999; Cherkin 2003), which have formed the basis for recommendations in clinical guidelines (Airaksinen 2006; Chou 2007; Manchikanti 2003; Staal 2003; van Tulder 2006; Waddell 2001). Most notably, these guidelines are largely dependent upon an earlier version of this Cochrane review (Assendelft 2003; Assendelft 2004). That review concluded that SMT was moderately superior to sham manipulation and therapies thought to be ineffective or harmful for acute or chronic low-back pain; however, the effect sizes were small and arguably not clinically relevant. Furthermore, SMT was found to be no more effective than other standard therapies (e.g. general practitioner care, analgesics, exercise, or back schools) for short or long-term pain relief or functional improvement for acute or chronic low-back pain.

Recommendations regarding SMT vary across national guidelines on the management of back pain (Koes 2001; van Tulder 2004). For example, SMT is considered to be a therapeutic option in the acute phase of low-back pain in many countries, while in other countries, such as the Netherlands, Australia, and Israel, it is not recommended (Koes 2001). Similarly, SMT is considered to be a useful option in the subacute or chronic phase in the Danish and Dutch guidelines, but is either not recommended or is absent in the other national guidelines.

The purpose of this review is to update the previous Cochrane review, using the most recent guidelines developed by the Cochrane Collaboration in general (Handbook 5 2008) and by the Cochrane Back Review Group in particular (Furlan 2009). In contrast to the previous Cochrane review, the review has been split into two parts by duration of the complaint, namely acute (Rubinstein 2010) and chronic low-back pain. The present review reports on chronic low-back pain only, based on the published protocol (Rubinstein 2009).

Description of the condition

Low-back pain is defined as pain and discomfort, localised below the costal margin and above the inferior gluteal folds, with or without referred leg pain. Chronic low-back pain is typically defined as pain persisting for more than 12 weeks (Spitzer 1987). Non-specific low-back pain is further defined as low-back pain not attributed to a recognizable, known specific pathology (e.g. infection, tumour, fracture or radicular syndrome).

Description of the intervention

SMT is considered here as any "hands-on" treatment, including both manipulation and mobilisation of the spine (Assendelft 2003; Assendelft 2004). Mobilisations use low-grade velocity, small or large amplitude passive movement techniques within the patient's range of motion and control. Manipulation, on the other hand, uses a high velocity impulse or thrust applied to a synovial joint over a short amplitude at or near the end of the passive or physiologic range of motion, which is often accompanied by an audible "crack" (Sandoz 1969). The cracking sound is caused by cavitation of the joint, which is a term used to describe the formation and activity of bubbles within the fluid (Evans 2002; Unsworth 1971). Various practitioners, including chiropractors, manual therapists (physiotherapists trained in manipulative techniques), orthomanual therapists (medical doctors trained in manipulative techniques) or osteopaths use this intervention in their practices. However, the diagnostic techniques and philosophy of the various professions differ. The focus of orthomanual medicine is on abnormal positions of the skeleton and symmetry in the spine, while manual therapy focuses on functional disorders of the musculoskeletal system, and chiropractic focuses on the musculoskeletal and nervous systems in relation to the general health of the patient (van de Veen 2005).

How the intervention might work

Many hypotheses exist regarding the mechanism of action for spinal manipulation and mobilization (Brønfort 2008; Khalsa 2006; Pickar 2002), and some have postulated that given their theoretically different mechanisms of action, mobilisation and manipulation should be assessed as separate entities (Evans 2002). The modes of action might be roughly divided into mechanical and neurophysiologic. The mechanistic approach suggests that SMT acts on a manipulable lesion (often called the functional spinal lesion or subluxation) which proposes that forces to reduce internal mechanical stresses will result in reduced symptoms (Triano 2001). However, given the non-nociceptive behaviour of chronic low-back pain, a purely mechanistic theory alone cannot explain clinical improvement (Evans 2002). Much of the literature focuses on the influence on the neurological system, where it is suggested that spinal manipulation therapy impacts the primary afferent neurons from paraspinal tissues, the motor control system and pain processing (Pickar 2002), although the actual mechanism remains debatable (Evans 2002; Khalsa 2006).

Why it is important to do this review

SMT is a worldwide, extensively practiced intervention provided by a variety of professions. However, the efficacy of this therapy for chronic low-back pain is not without dispute. This review, with its comprehensive and rigorous methodology, is thought to provide better insight into this problem. Although numerous systematic reviews have examined the efficacy of SMT for low-back pain (Airaksinen 2006; Chou 2007), very few have conducted a meta-analysis, especially for chronic low-back pain. Also, many of the reviews were narrative rather than systematic and the results were not consistent (Assendelft 1998). The previous version of the Cochrane review was published in 2004 and since then many new trials have been published, including some with large numbers of participants. In addition, the methodology of systematic reviews has recently been updated (Handbook 5 2008), as well as the specific guidelines for reviews of back and neck pain (Furlan 2009).

OBJECTIVES

The objective of this review was to examine the effectiveness of SMT on pain, functional status and recovery at the short-, intermediate- and long-term follow-up measurements as compared to control treatments (e.g. no treatment, sham and all other treatments) for adults with chronic low-back pain.

METHODS

Criteria for considering studies for this review

Types of studies

Only randomised studies were included. Studies using an inadequate randomisation procedure (e.g. alternate allocation, allocation based upon birth date) were excluded.

Types of participants

Inclusion criteria

- Adult participants (≥ 18 years of age) with low-back pain with a mean duration for the current episode (for the study population) longer than 12 weeks, meaning more than 50% of the study population had pain that had lasted longer than three months.
- Studies with patients from primary, secondary or tertiary care
- Patients with or without radiating pain

Exclusion criteria

Subjects with:

- Post-partum low-back pain or pelvic pain due to pregnancy
- Pain not related to the low-back, e.g. coccydynia
- Post-operative studies or subjects with "failed-back syndrome"

or studies which

- Examined "maintenance care" or prevention
- Were designed to test the immediate post-intervention effect of a single treatment only, with no additional follow-up (because we were interested in the effect of SMT beyond one day).
- Exclusively examined specific pathologies, e.g. sciatica.

Note: Studies of sciatica were excluded because it has been identified by many as a prognostic factor associated with a poor outcome (Bouter 1998; Brønfort 2004b), especially with SMT (Axen 2005; Malmqvist 2008). Sciatica was defined here as radiating pain following the sciatic distribution and exhibiting signs of a radiculopathy.

Types of interventions

Experimental intervention

The experimental intervention examined in this review includes both spinal manipulation and mobilisation for chronic low-back pain. Unless otherwise indicated, SMT refers to both "hands-on" treatments.

Types of comparison

Studies were included for consideration if the study design used suggested that the observed differences were due to the unique contribution of SMT. This excludes studies with a multi-modal treatment as one of the interventions (e.g. standard physician care + spinal manipulation + exercise therapy) and a different type of intervention or only one intervention from the multi-modal therapy as the comparison (e.g. standard physician care alone), thus rendering it impossible to decipher the effect of SMT. However, studies comparing SMT in addition to another intervention compared to that same intervention alone were included.

Comparison therapies were combined into the following main clusters:

1) SMT *versus* inert interventions
2) SMT *versus* sham SMT
3) SMT *versus* all other interventions
4) SMT in addition to any intervention *versus* that intervention alone

Inert interventions included, for example, detuned diathermy and detuned ultrasound. "All other interventions" included both presumed effective and ineffective interventions for treatment of chronic low-back pain. Determination of what interventions were

considered ineffective and effective was based upon the literature and our interpretation of those results (Airaksinen 2006; Chou 2007).

Types of outcome measures

Only patient-reported outcome measures were evaluated. Physiological measures, such as spinal flexibility or degrees achieved with a straight leg raise test (i.e. Lasègue sign) were not considered clinically-relevant outcomes and were not included.

Primary outcomes

- pain expressed on a self-reported scale (e.g. visual analogue scale (VAS), numerical rating scale (NRS))
- functional status expressed on a back-pain specific scale (e.g. Roland-Morris Disability Questionnaire, Oswestry Disability Index)
- global improvement or perceived recovery (recovered is defined as the number of patients reported to be recovered or nearly recovered)

Secondary outcomes

- health-related quality of life (e.g. SF-36 (as measured by the general health sub-scale), EuroQol, general health (e.g. as measured on a VAS scale) or similarly validated index)
- return-to-work

Search methods for identification of studies

Electronic searches

We identified RCTs and systematic reviews by electronically searching the following databases:

- CENTRAL (*The Cochrane Library 2009,* issue 2) (Appendix 1)
- MEDLINE from Jan. 2000- June 2009 (Appendix 2)
- EMBASE from Jan. 2000- June 2009 (Appendix 3)
- CINAHL from Jan. 2000- June 2009 (Appendix 4)
- PEDro up to June 2009
- Index to Chiropractic Literature up to June 2009

The search strategy developed by the Cochrane Back Review Group was followed, using free text words and MeSH headings (Furlan 2009). A search was not conducted for studies published before 2000 because they were included in the previous Cochrane review (Assendelft 2003; Assendelft 2004).

Searching other resources

In addition to the aforementioned, we also 1) screened the reference lists of all included studies and systematic reviews pertinent to this topic; and 2) searched the main electronic sources of ongoing trials (National Research Register, meta-Register of Controlled Trials; Clinical Trials).

Data collection and analysis

Selection of studies

Two review authors with a background in chiropractic (SMR) and movement science (MvM) independently screened the titles and abstracts from the search results. Potentially relevant studies were obtained in full text and independently assessed for inclusion. Disagreements were resolved through discussion. A third review author (MWvT) was contacted if an arbiter was necessary. Only full papers were evaluated. Abstracts and proceedings from congresses or any other "grey literature" were excluded. There were no language restrictions.

Data extraction and management

A standardised form was used to extract data from the included papers. The following data were extracted: study design (RCT), study characteristics (e.g. country where the study was conducted, recruitment modality, source of funding, risk of bias), patient characteristics (e.g. number of participants, age, gender), description of the experimental and control interventions, co-interventions, duration of follow-up, types of outcomes assessed, and the authors' results and conclusions. Data were extracted independently by the same two review authors who conducted the selection of studies. Any disagreements were discussed and an arbiter (MWvT) consulted when necessary. Key findings were summarized in a narrative format. Data relating to the primary outcomes were assessed for inclusion in the meta-analyses and final value scores (means and standard deviations) were extracted. Change scores were converted to a mean value for the respective follow-up measurement. Outcomes were assessed at one, three, six and twelve months and data included according to the time closest to these intervals. Only one study examined data beyond 12 months (Goldby 2006).

Assessment of risk of bias in included studies

The risk of bias (RoB) assessment for RCTs was conducted using the twelve criteria recommended by the Cochrane Back Review Group and evaluated independently by same two review authors mentioned above (SMR, MvM). These criteria are standard for evaluating effectiveness of interventions for low-back pain (Appendix 5; Furlan 2009). The criteria were scored as "low risk", "high risk" or "unclear risk" and reported in the *Risk of Bias* table. Any disagreements between the review authors were resolved

by discussion, including input from a third independent review author (MWvT). In virtually all cases, an attempt was made to contact authors for clarification of methodological issues if the information was unclear. A study with a low RoB was defined as one fulfilling six or more of the criteria items, which is supported by empirical evidence (van Tulder 2009), and with no fatal flaw, which is defined as those studies with 1) a drop-out rate greater than 50% at the first and subsequent follow-up measurements; or 2) statistically and clinically-relevant important baseline differences for one or more primary outcomes (i.e. pain, functional status) indicating unsuccessful randomisation. Quantitative data from studies with a fatal flaw were excluded from the meta-analyses (see risk of bias in the included studies). Since the review authors were already familiar with the literature, they were not blinded to authors of the individual studies, institution or journal.

Blinding the patient and practitioner to treatment allocation is nearly impossible in trials of SMT. Given that the primary outcomes assessed in this review are all subjective measures (i.e. pain, functional status, perceived recovery), any attempt to blind the outcome assessor was considered irrelevant because the patient is viewed to be the outcome assessor when evaluating subjective measures. Therefore, if the patient is not blinded, the outcome assessor was also considered not blinded. However, to drop these items from the assessment is to negate the observation that "blinding" of research personnel and participants provides less biased data.

Measures of treatment effect

Treatment effect was examined through meta-analyses, but these were only conducted if studies were thought to be clinically homogenous. Clinical homogeneity was defined *a priori* by setting, population and comparison group. A mean difference (MD) was calculated for pain and when necessary, VAS or NRS scales were converted to a 100-point scale. Other scales were allowed if it was thought that the construct measured was consistent with the outcome being evaluated. For functional status, a standardized mean difference (SMD) was calculated because many different instruments were used (e.g. Roland-Morris Disability Questionnaire (RMDQ), Oswestry Disability Index (ODI), disability sub-scale of the von Korff scale, Disability Rating Index (DRI)). A negative effect size indicates that SMT is more beneficial than the comparison therapy, meaning subjects have less pain and better functional status. Quality of life was analysed by a standardized mean difference. Where necessary, scores were transformed, so that a higher score indicates a better outcome, which is how this was typically measured; therefore, a negative effect size indicates that the contrast therapy is more beneficial. For dichotomous outcomes (i.e. recovery, return-to-work), a risk ratio (RR) was calculated and the event defined as the number of subjects recovered or returned-to-work. A positive RR indicates that SMT results in a greater chance of recovery or return-to-work. A random-effects model was used for all analyses because a substantial amount of heterogeneity remained unexplained by the subgroup and sensitivity analyses. Funnel plots were only examined for publication bias for the comparison, SMT *versus* all other interventions, due to the fact that the other comparisons included too few studies. For each treatment comparison, an effect size and a 95% confidence interval (CI) were calculated. All analyses were conducted in Review Manager 5.0.

Assessment of clinical relevance. The determination of clinical relevance was evaluated by one question, "Is the size of the effect clinically relevant?". Levels of clinical relevance were defined as: 1) Small: MD < 10% of the scale (e.g. < 10 mm on a 100-mm VAS); SMD or "d" scores $\leq$ 0.2; Relative risk, < 1.25 or > 0.8; 2) Medium: MD 10% to 20% of the scale, SMD or "d" scores = 0.5, Relative risk between 1.25 to 2.0 or 0.5 to 0.8; 3) Large: MD > 20% of the scale, SMD or "d" scores $\geq$ 0.8, Relative risks > 2.0 or < 0.5 (Cohen 1988; Handbook 5 2008).

Unit of analysis issues

We attempted to combine data in studies with multiple comparisons where it was thought that similar contrasts were used and the outcomes were thought to be clinically similar. This was conducted for one study (Ferreira 2007), which included two similar forms of exercise as the contrast to SMT, general exercise and motor control exercise. In all other cases, when multiple contrasts were examined in the same comparison (e.g. SMT versus physiotherapy versus standard medical care), the number of subjects in the shared comparison, SMT, were halved. This step corrects for error introduced by "double-counting" of subjects for the "shared comparison" in the meta-analyses. Another study presented data from a cross-over trial (Evans 1978), in which case, data were presented prior to the crossover of the intervention.

Dealing with missing data

In cases where data were reported as a median and interquartile range (IQR), it was assumed that the median was equivalent to the mean and the width of the IQR equivalent to 1.35 times the standard deviation (Handbook 5 2008, section 7.7.3.5). In one study (Gibson 1985), a range was presented along with the median instead of a IQR, in which case, the standard deviation was estimated to be one-quarter of the range, although we recognize that this method is not robust and potentially subject to error Handbook 5 2008, section 7.7.3.6). In another study (Koes 1992), data were presented together for neck and low-back pain. A subsequent stratified analysis had been performed for the low-back pain data, but was no longer available. However, we were able to extract the results from a recent systematic review (Brønfort 2008), which presented these data as between-group differences. Where data were reported in a graph and not in a table, the means and standard deviations were estimated. When standard deviations were not reported, an attempt was made to contact the author. In the absence of additional information, these were calculated from the confidence intervals, where possible. If the standard deviation for follow-up measurements was missing, its baseline measure was

used for the subsequent follow-ups. Finally, if no measure of variation was reported anywhere in the text, the standard deviation was estimated based upon other studies with a similar population and RoB.

Assessment of heterogeneity

Heterogeneity was explored in two manners, informally by vision (eye-ball test) and formally tested by the Q-test (chi-square) and I^2; however, the decision regarding heterogeneity was dependent upon the I^2 (Handbook 5 2008). Substantial heterogeneity is defined as $\geq$ 50%, and where necessary, the effect of the interventions are described if the results are too heterogenous.

Data synthesis

The overall quality of the evidence and strength of recommendations was evaluated using GRADE (Guyatt 2008). The quality of the evidence for a specific outcome was based upon performance against five principal domains: 1) limitations in design (downgraded when > 25% of the participants were from studies with a high RoB), 2) inconsistency of results (downgraded in the presence of significant statistical heterogeneity (I^2 > 50%) and inconsistent findings (in the presence of widely differing estimates of the treatment effect, that is, individual studies favouring either the intervention or control group)), 3) indirectness (i.e. generalisability of the findings; downgraded when > 50% of the participants were outside the target group, for example, studies which exclusively examined older subjects or included inexperienced treating physicians), 4) imprecision (downgraded when the total number of participants was less than 400 for each continuous outcome and 300 for dichotomous outcomes) and 5) other (e.g. publication bias). Single studies (N < 400 for continuous outcomes,< 300 for dichotomous outcomes) were considered inconsistent and imprecise and provide "low quality evidence", which could be further downgraded to "very low quality evidence" if there were also limitations in design or indirectness. Summary of Findings tables were generated for the primary analyses and for the primary outcome measures only, regardless of statistical heterogeneity, but when present, this was noted. The quality of the evidence is described as:
*High quality:*Further research is very unlikely to change our confidence in the estimate of effect. There are sufficient data with narrow confidence intervals. There are no known or suspected reporting biases.
*Moderate quality:*Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate; one of the domains is not met.
*Low quality:*Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate; two of the domains are not met
*Very low quality:*Great uncertainty about the estimate; three of the domains are not met.
No evidence: No evidence from RCTs.

Subgroup analysis and investigation of heterogeneity

Regardless of possible heterogeneity of the included studies, the following stratified analyses were conducted: 1) By control groups as defined in *Types of intervention* (see *Types of comparisons*); and 2) by time, that is, short-term (closest to one to three months), intermediate (closest to six months) and long-term follow-up (closest to 12 months).

Sensitivity analysis

The following sensitivity analyses were planned *a priori* and conducted in order to explain possible sources of heterogeneity between studies: 1) for RoB; 2) for studies with an adequate allocation procedure; 3) by duration of the low-back pain (studies which included subacute and chronic *versus* studies of exclusively chronic low-back pain); 4) by type of technique (high-velocity low amplitude manipulation); 5) by type of manipulator (chiropractor *versus* manual therapist or physiotherapist); and 6) by type of comparison therapy ((presumed ineffective therapies (e.g. diathermy, ultrasound, single counselling session with advice on back pain) and presumed effective therapies (e.g. exercise, standard medical care, physiotherapy)). In addition, a specific type of contrast (i.e. exercise therapy) was examined *posteriori* because it was thought to be an important contrast, but not earlier defined in the protocol. Summary forest plots were constructed in STATA v.10, which depict these results.

RESULTS

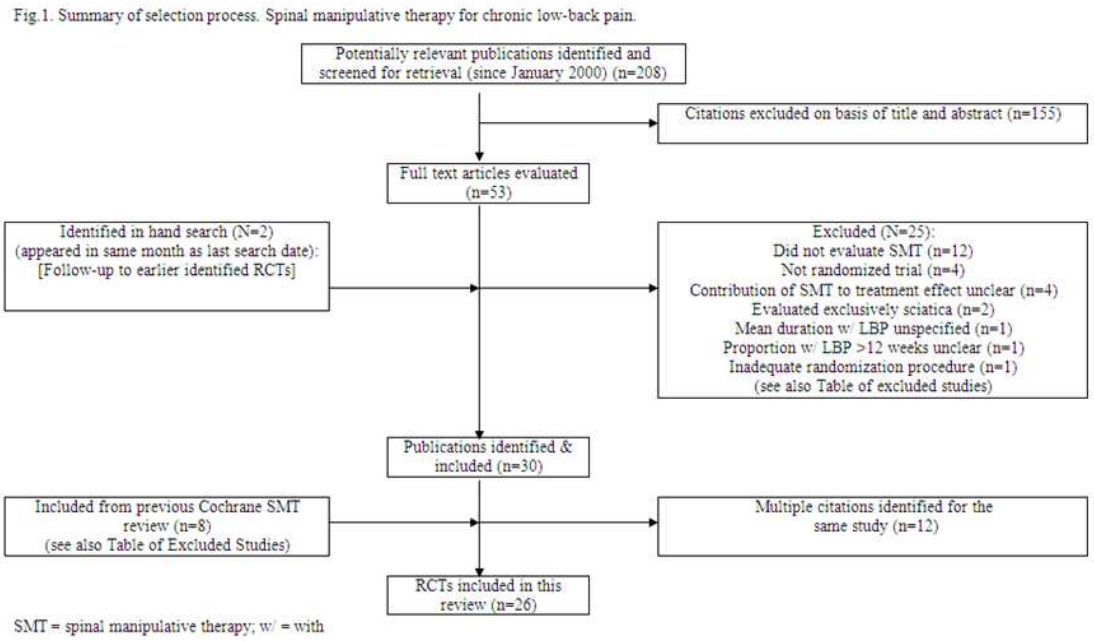
Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification; Characteristics of ongoing studies.
See Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

Results of the search

Since the publication of the previous review, 18 new trials were identified which fulfilled the inclusion criteria (Chown 2008; Ferreira 2007; Ghroubi 2007; Goldby 2006; Gudavalli 2006; Hondras 2009; Hsieh 2002; Hurwitz 2002; Licciardone 2003; Mohseni-Bandpei 2006; Muller 2005; Paatelma 2008; Rasmussen 2008; Rasmussen-Barr 2003; Skillgate 2007; UK BEAM trial 2004; Wilkey 2008; Zaproudina 2009, thus this review represents a majority of studies published in the past decade. Eight trials from the previous review are included (Brønfort 1996; Evans 1978; Gibson 1985; Koes 1992; Pope 1994; Postacchini 1988; Waagen 1986), one of which recently published long-term results (Hemmila 2002) Figure 1.

Figure 1. Summary of selection process. Spinal manipulative therapy for chronic low-back pain.



The countries in which the studies were conducted varied, but were largely limited to North America and Europe. Eight studies were conducted in the USA (Brønfort 1996; Gudavalli 2006; Hondras 2009; Hsieh 2002; Hurwitz 2002; Licciardone 2003; Pope 1994; Waagen 1986), seven studies in the UK (Chown 2008; Evans 1978; Gibson 1985; Goldby 2006; Mohseni-Bandpei 2006; UK BEAM trial 2004; Wilkey 2008), five in Finland (Hemmila 2002; Paatelma 2008; Rasmussen-Barr 2003; Skillgate 2007; Zaproudina 2009), two in Australia (Ferreira 2007; Muller 2005), one in Denmark (Rasmussen 2008), one in Italy (Postacchini 1988), one in the Netherlands (Koes 1992) and one in Tunesia (Ghroubi 2007). All trials were published in English except the trial conducted in Tunesia, which was published in French.

Included studies

In total, 6070 patients were examined in the trials. Study sample sizes ranged from 29 to 1,334 (median (IQR) = 149 (86 to 244). *Types of studies.* In total, four studies were identified which compared SMT to a placebo in the form of an anti-oedema gel spread over the lumbar region (Postacchini 1988) or other inert interventions (i.e. detuned short-wave diathermy (Gibson 1985); detuned ultrasound (Koes 1992); corset and transcutaneous muscle stimulation (Pope 1994)); three studies which compared SMT to sham SMT (Ghroubi 2007; Licciardone 2003; Waagen 1986); 21 studies which compared SMT to any other intervention - both presumed effective or ineffective (i.e. acupuncture (Muller 2005), back school (Hsieh 2002; Postacchini 1988), educational back booklet with or without additional counselling (Goldby 2006; Paatelma 2008), exercise therapy (Brønfort 1996; Chown 2008; Ferreira 2007; Goldby 2006; Gudavalli 2006; Hemmila 2002; Paatelma 2008; Rasmussen-Barr 2003; UK BEAM trial 2004), myofascial therapy (Hsieh 2002), massage (Pope 1994), pain clinic (Wilkey 2008), pharmaceutical/analgesic therapy only (Muller 2005; Postacchini 1988), short-wave diathermy (Gibson 1985), standard medical care, consisting of among other things, analgesic therapy and advice/reassurance (Hondras 2009; Hurwitz 2002; Koes 1992; Skillgate 2007), standard physiotherapy (Hemmila 2002; Hurwitz 2002; Koes 1992; Postacchini 1988; Zaproudina 2009), and ultrasound (Mohseni-Bandpei 2006)); and five studies which compared SMT plus another intervention to the intervention alone (i.e. analgesic therapy (Evans 1978), exercise (Rasmussen 2008), myofascial therapy (Hsieh 2002), standard

medical care and in combination with exercise (UK BEAM trial 2004) and usual care (Licciardone 2003)).

Study population. The included studies represent a rather heterogenous population with regard to duration of pain, presence or absence of radiating pain, and distribution of age (Table 1). Most studies included middle-aged subjects with or without radiating pain. One study included subjects over 55 years (Hondras 2009), and two studies included subjects without radiating pain (Ghroubi 2007; Muller 2005). However, in a number of studies it was not clear if subjects with radiating pain were included or not (Gibson 1985; Goldby 2006; Mohseni-Bandpei 2006; Skillgate 2007; Waagen 1986). Relatively few studies examined exclusively chronic low-back pain (that is, an inclusion criteria which specified that the symptoms must have been present for three months or longer) (Chown 2008; Ferreira 2007; Goldby 2006; Gudavalli 2006; Licciardone 2003; Mohseni-Bandpei 2006; Muller 2005; Rasmussen 2008; Wilkey 2008); however, most studies indicated that patients had a current episode of low-back pain consisting of months to years.

Technique: type, practitioner, number and duration of treatment. The type of technique, type of treating physician/therapist, and number and duration of the treatments also varied. In ten studies, treatment was delivered by a chiropractor (Brønfort 1996; Gudavalli 2006; Hondras 2009; Hsieh 2002; Hurwitz 2002; Muller 2005; Pope 1994; Postacchini 1988; Waagen 1986; Wilkey 2008), in five, by a manual or physical therapist (Ferreira 2007; Goldby 2006; Koes 1992; Mohseni-Bandpei 2006; Rasmussen-Barr 2003), in three, by an osteopath (Chown 2008; Gibson 1985; Licciardone 2003), in three, by a medical manipulator or orthomanual therapist (Evans 1978; Paatelma 2008; Rasmussen 2008), in two, by a bone-setter (Hemmila 2002; Zaproudina 2009), in one, by a naprapath (Skillgate 2007), and in one, by a number of different disciplines (UK BEAM trial 2004). In another study, it was unclear what type of SMT treatment was delivered and what the level or skill of the treating physicians was (Ghroubi 2007). In virtually all studies, treatment was delivered by a few select experienced physicians/therapists, with the exception of the UK BEAM study (UK BEAM trial 2004), where participants were treated in the manipulative-arm of the study in 45 clinics by as many as 84 practitioners of various professions. In another study, treatment was delivered by a few select pre-doctoral osteopathic manipulative medicine fellows, who could be considered inexperienced in manipulative treatments (Licciardone 2003).

The primary type of (thrust) technique used in the SMT arm of the studies varied highly and was defined as a high-velocity low-amplitude thrust (Brønfort 1996; Chown 2008; Hondras 2009; Hsieh 2002; Hurwitz 2002; Licciardone 2003; Muller 2005; Paatelma 2008; Pope 1994; Rasmussen 2008; UK BEAM trial 2004; Waagen 1986), Maitland mobilization (Ferreira 2007; Mohseni-Bandpei 2006), mobilization consisting of flexion-distraction (Gudavalli 2006; Hondras 2009), unspecified mobilization (Hemmila 2002; Rasmussen-Barr 2003), unspecified rotational thrust technique (Evans 1978; Gibson 1985), unspecified technique (Ghroubi 2007; Goldby 2006; Koes 1992; Postacchini 1988; Skillgate 2007; Zaproudina 2009) or allowed various types of thrust and/or non-thrust techniques to be used within the study (Wilkey 2008).

It is unclear how many treatments the participants received on average because studies did not typically report this. The maximum number of treatments allowed by protocol was, on average, eight (SD = 4; data from 24 studies). In other studies, this was at the discretion of the therapist/physician and terminated sooner if the patient recovered (Table 1). Similarly, the treatment period was also quite varied. The duration of the treatment was protocolized for, on average, seven weeks (SD = 4; data from 23 studies).

Outcome measures: types, timing. All but one study reported on pain (Chown 2008). All studies measured this construct via a VAS or NRS, with the exception of two (Skillgate 2007; UK BEAM trial 2004), which used the pain sub-scale from the modified von Korff scale. Most studies reported back-pain specific functional status, consisting of either the Roland-Morris Disability Questionnaire (Brønfort 1996; Ferreira 2007; Gudavalli 2006; Hondras 2009; Hsieh 2002; Hurwitz 2002; Licciardone 2003; Paatelma 2008;UK BEAM trial 2004; Wilkey 2008) or Oswestry Disability Index (Chown 2008; Goldby 2006; Hemmila 2002; Mohseni-Bandpei 2006; Muller 2005; Rasmussen-Barr 2003; Zaproudina 2009); however, other scales were also used, such as the modified von Korff scale (Skillgate 2007) (disability data presented separately), Disability Rating Index (Rasmussen-Barr 2003) and a four-point non-validated scale (Postacchini 1988). Slightly more than one-third of the studies reported on some aspect of perceived recovery (Brønfort 1996; Evans 1978; Ferreira 2007; Gibson 1985; Gudavalli 2006; Hondras 2009; Hurwitz 2002; Koes 1992; Skillgate 2007; Zaproudina 2009); however, these data were not always able to be extracted because it was expressed for example, as a continuous variable (Ferreira 2007;Hondras 2009; Koes 1992) or was not presented separately for the low back (Skillgate 2007). Relatively few studies reported on the secondary outcomes, such as return-to-work or aspects thereof, such as number of sick-leave days (Brønfort 1996; Gibson 1985; Hemmila 2002; Hsieh 2002; Licciardone 2003), costs associated with care (Gudavalli 2006; Hemmila 2002; UK BEAM trial 2004), or health-related quality of life (HRQoL) such as via the SF-36 (Gudavalli 2006; Hondras 2009; Hsieh 2002; Licciardone 2003; Muller 2005; UK BEAM trial 2004), EuroQoL (Chown 2008; UK BEAM trial 2004), HRQoL - 15D questionnaire (Zaproudina 2009), Nottingham Health Profile (Goldby 2006), general health status (expressed on a 10 cm VAS scale) (Rasmussen-Barr 2003) and other (Dartmouth Primary Care Cooperative Information Project chart system (i.e. COOP)) (Brønfort 1996). In addition, when the SF-36 was measured, data were not always available for the general health subscale, as some studies reported either an overall score (Hondras 2009; Hsieh 2002; Licciardone 2003) or presented other subscales (UK BEAM trial 2004). One study (Koes 1992) examined

a mixed population (neck and low-back); data are presented for the low-back only.

Timing of the outcome measures ranged from two weeks to two years post-randomisation. The majority reported short- and intermediate-term outcomes, although many reported long-term outcomes as well.

Safety. Slightly more than one-third of the studies reported on adverse events (Brønfort 1996; Evans 1978; Gudavalli 2006; Hondras 2009; Hsieh 2002; Muller 2005; Rasmussen 2008; Skillgate 2007; UK BEAM trial 2004). Adverse events in the SMT group were limited to muscle soreness, stiffness, and/or transient increase in pain. None of the studies registered any serious complications in either the experimental or control group.

Excluded studies

Many studies were excluded because either the proportion of subjects with chronic low-back pain was unclear or unspecified (Andersson 1999; Beyerman 2006 Coxhead 1981; Doran 1975; Glover 1974; Herzog 1991; Kinalski 1989; MacDonald 1990; Meade 1990/1995; Rupert 1985; Shearar 2005; Sims-Williams 1978; Triano 1995; Zylbergold 1981); the mean duration of symptoms for the population was less than 12 weeks (i.e. 50% of the population with less than 12 weeks of low-back pain) (Brønfort 1989; Cherkin 1998; Hoehler 1981; Mathews 1987; Skagren 1997); the contribution of SMT to the treatment effect could not be discerned (Aure 2003; Haas 2004; Niemisto 2003/2005; Ongley 1987); the procedure of randomisation and allocation was clearly inappropriate (Arkuszewski 1986; Coyer 1955; Hough 2007; Nwuga 1982; Petty 1995); the study evaluated exclusively subjects with specific pathology, such as sciatica (Brønfort 2004; Burton 2000; Coxhead 1981), the study included post-surgical patients (Timm 1994) or the study did not evaluate SMT as defined here (Geisser 2005).

Risk of bias in included studies

The results of the RoB for the individual studies are summarized in Figure 2. In total, nine of the 26 trials met the criteria for a low RoB (Brønfort 1996; Ferreira 2007; Hemmila 2002; Hondras 2009; Hsieh 2002; Hurwitz 2002; Koes 1992; Skillgate 2007; UK BEAM trial 2004). In total, three studies, all with a high RoB, were identified with a fatal flaw and excluded from the meta-analyses: two studies (Chown 2008; Muller 2005) had more than 50% drop-out at the first follow-up measurement and one study (Goldby 2006) was found to have clinically-relevant baseline differences between the interventions for one or more primary outcomes suggesting that randomisation was not properly conducted.

Figure 2. Risk of bias summary: Summary of authors' judgement on risk of bias items within each included study.

The following professions were represented in those studies with a low RoB: bone-setters (Hemmila 2002), chiropractors (Brønfort 1996; Hondras 2009; Hsieh 2002; Hurwitz 2002), manual/physical therapists (Koes 1992; Ferreira 2007), naprapaths (Skillgate 2007) and combination of various professionals (i.e. chiropractors, physiotherapists and osteopaths) (UK BEAM trial 2004).

Allocation

Slightly less than half of the studies used both an adequate sequence generation and allocation procedure (Brønfort 1996; Ferreira 2007; Gudavalli 2006; Hemmila 2002; Hondras 2009; Hurwitz 2002; Koes 1992; Skillgate 2007; UK BEAM trial 2004; Wilkey 2008; Zaproudina 2009). In seven studies, both randomisation and allocation was unclear (Evans 1978; Gibson 1985; Mohseni-Bandpei 2006; Postacchini 1988; Rasmussen 2008; Waagen 1986).

Blinding

In total, three studies attempted to blind patients to the assigned intervention by providing a sham treatment (Ghroubi 2007; Licciardone 2003; Waagen 1986). Of these, only one evaluated the success of blinding post-treatment (Waagen 1986), which was at the two-week follow-up. In that study, 52% (N = 15/29) of the participants completed a post-treatment evaluation of the success of the blinding: 17% (N = 1/6) from the experimental group thought they had received sham SMT, while 67% (N = 6/9) from the sham group thought that they had received SMT, suggesting that perhaps blinding was partially successful, although this might represent a biased response given the relatively low response rate.

Incomplete outcome data

Half of the studies provided an adequate overview of withdrawals or drop-outs and were able to keep these to a minimum for the subsequent follow-up measurements, although not all of these conducted long-term follow-up (Evans 1978; Ferreira 2007; Ghroubi 2007; Gibson 1985; Goldby 2006; Hemmila 2002; Hsieh 2002; Hurwitz 2002; Koes 1992; Pope 1994; Skillgate 2007; Wilkey 2008; Zaproudina 2009). In another study, there was a difference in the drop-out rate between groups (Goldby 2006).

Selective reporting

Published or registered protocols were available for relatively few studies (Ferreira 2007; Hondras 2009; Skillgate 2007; UK BEAM trial 2004; Zaproudina 2009), despite an extensive and comprehensive search, which included searching for registered clinical trials in www.clinicaltrials.gov, ISRCTN and other trial registries. In the absence of these, it was difficult for us to determine whether outcomes were measured, but not reported because they were found to be insignificant or unfavourable. Therefore, studies reporting all three primary outcomes (i.e. pain, back-pain specific functional status, and perceived recovery) were considered to have fulfilled this criterion. Only one study was identified with no published protocol or registered in one of the main trial registries, but reported all three primary outcomes (Hurwitz 2002).

Other potential sources of bias

Publication bias. An examination of publication bias was possible for only one comparison, SMT *versus* any other intervention, due to the paucity of data for the other comparisons. Funnel plots were constructed for the outcomes, pain and functional status Figure 3; Figure 4 respectively. For the outcome pain, it might appear that small studies favouring SMT are missing. This may indicate publication bias because some studies may have used SMT as a control group in a trial evaluating the effects of another intervention.

Figure 3. Funnel plot of comparison: 3. SMT vs. any other intervention, outcome: 3.1 Pain. Negative values favour SMT; positive values favour the control intervention.

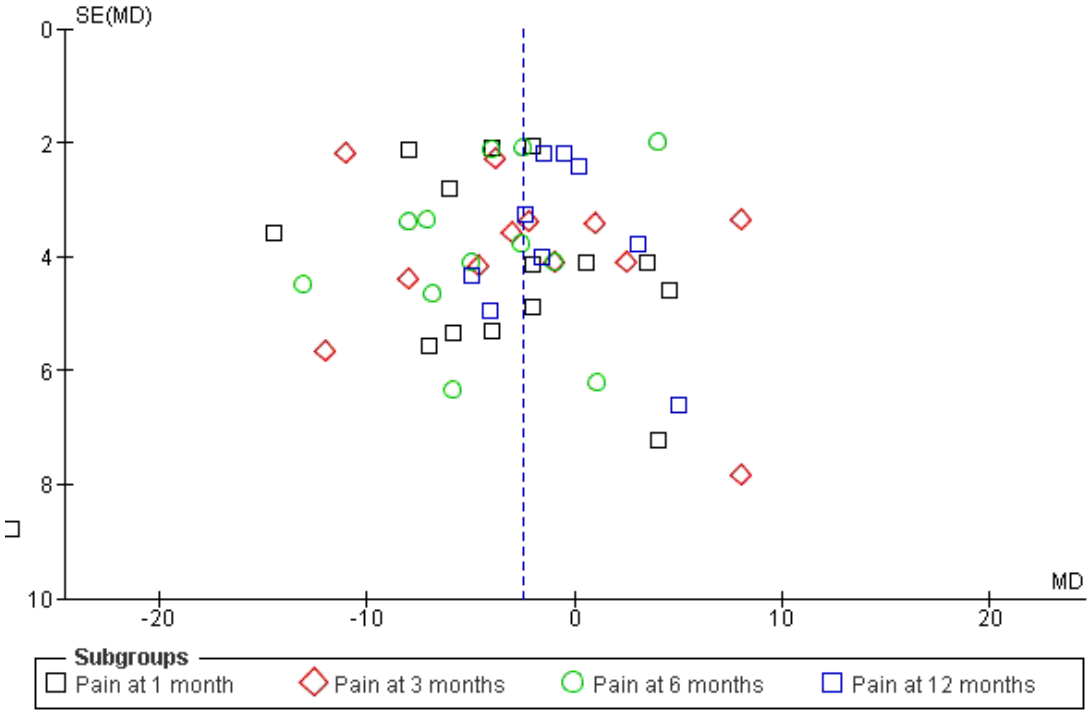
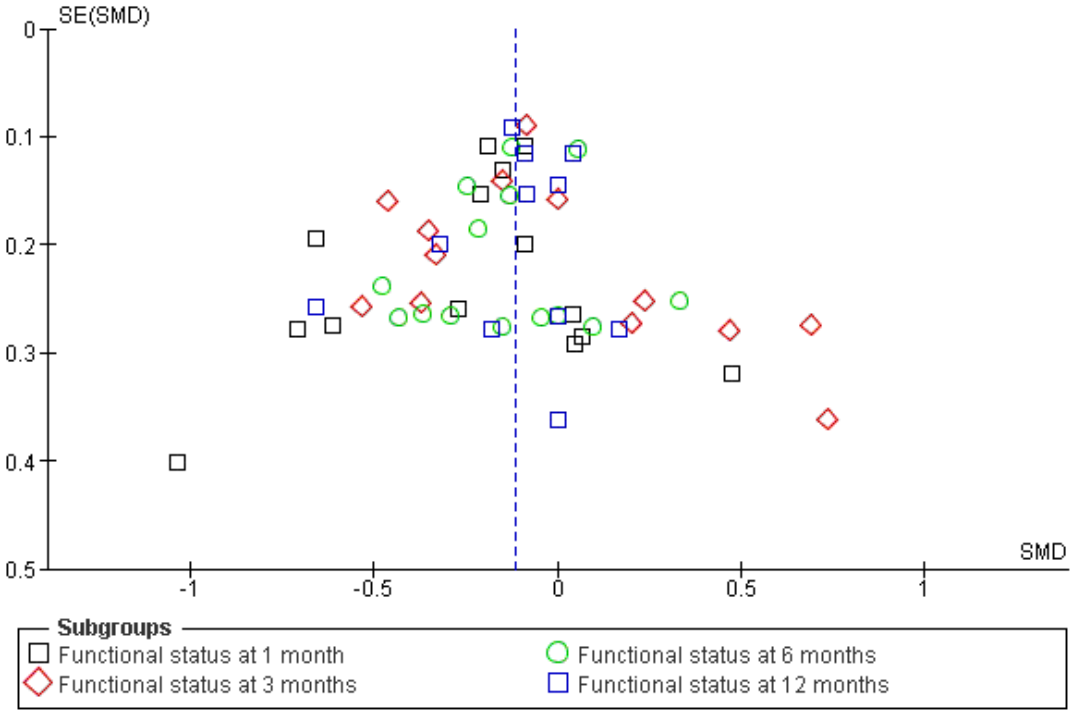


Figure 4. Funnel plot of comparison: 3. SMT vs. any other intervention, outcome: 3.2 Functional status. Negative values favour SMT; positive values favour the control intervention.



Effects of interventions

See: **Summary of findings for the main comparison** Spinal manipulative therapy compared to inert interventions for chronic low-back pain; **Summary of findings 2** spinal manipulative therapy (SMT) compared to sham SMT for chronic LBP; **Summary of findings 3** Spinal manipulative therapy compared to all other interventions for chronic low-back pain; **Summary of findings 4** spinal manipulative therapy plus any intervention compared to the intervention alone for chronic LBP

Primary analyses

Summary effect estimates are presented when there was no substantial heterogeneity. Summary of Findings tables are presented in Summary of findings for the main comparison (SMT versus inert interventions), Summary of findings 2 (SMT versus sham SMT), Summary of findings 3 (SMT versus all other interventions), Summary of findings 4 (SMT plus an intervention versus the intervention alone).

Effect of SMT versus inert interventions

In total, four studies (Gibson 1985; Koes 1992; Pope 1994; Postacchini 1988) were identified, one of which had a low RoB (Koes 1992). Based upon one study (Gibson 1985) (72 participants), there is very low quality evidence (high RoB, inconsistency, imprecision) that there is no significant difference between SMT and inert interventions (i.e. detuned short-wave diathermy and detuned ultrasound) for pain relief at one and three months (MD: -6.00, 95% CI: -15.82 to 3.82; MD: 7.00, 95% CI: -3.58 to 17.58, respectively) (Analysis 1.1). For recovery, one study (Gibson 1985) (72 participants) with a high RoB, was identified. There is very low quality evidence (high RoB, inconsistency, imprecision) that there is no significant difference between SMT and inert interventions at one and three months (RR: 1.03, 95% CI: 0.49 to 2.19; RR: 0.96, 95% CI: 0.56 to 1.65, respectively) (Analysis 1.2). For return-to-work, one study (Gibson 1985), with a high RoB, was identified. There is also very low quality evidence (high RoB, inconsistency, imprecision) that there is no significant difference at one or three months (RR: 1.29, 95% CI: 1.00 to 1.65; RR: 1.17, 95% CI:0.97 to 1.40, respectively) (Analysis 1.3). No data were available for functional status or health-related quality of life.

Three studies (Koes 1992; Pope 1994; Postacchini 1988) were identified for which data for the meta-analyses could not be ex-

tracted. One study (Koes 1992, N = 76) demonstrated a significant difference in improvement (P < 0.05) between SMT and detuned physiotherapy modalities at six weeks, but not three months. Another study (Pope 1994, N = 127) demonstrated no statistically significant difference in pain (P < 0.05) between SMT and use of a corset or transcutaneous muscle stimulation. Due to poor reporting, it is unclear from the study from Postacchini 1988 (N = 95) whether there was a statistically significant difference in improvement between SMT and a placebo group (i.e. anti-oedema gel) at three weeks or six months.

Effect of SMT versus sham SMT

In total, three studies (Ghroubi 2007; Licciardone 2003; Waagen 1986) were identified, all with a high RoB. There was substantial heterogeneity for pain at one month, thus the results are described here. Two studies (Ghroubi 2007; Waagen 1986) demonstrated a non-significant effect in favour of SMT, while another study (Licciardone 2003) demonstrated a non-significant effect in favour of sham SMT. All examined different forms of SMT, that is, unspecified SMT, osteopathic SMT and chiropractic SMT, respectively, and all were relatively small studies. For pain relief, based upon one study (Licciardone 2003) (55 participants), there is very low quality evidence (high RoB, inconsistency, indirectness, imprecision) that there is no significant difference between SMT and sham SMT at three and six months (MD: 2.50, 95% CI: -9.64 to 14.64; MD: 7.10, 95% CI: -5.16 to 19.36, respectively) (Analysis 2.1). For functional status, based upon the aforementioned study (Licciardone 2003), there is also very low quality evidence (high RoB, inconsistency, indirectness, imprecision) that there is no significant difference at one, three or six months (SMD: -0.45, 95% CI: -0.97 to 0.06; SMD: 0.00, 95% CI: -0.56 to 0.56; SMD: 0.04, 95% CI: -0.52 to 0.61) (Analysis 2.2). No data were available from any study on recovery, return-to-work, or health-related quality of life.

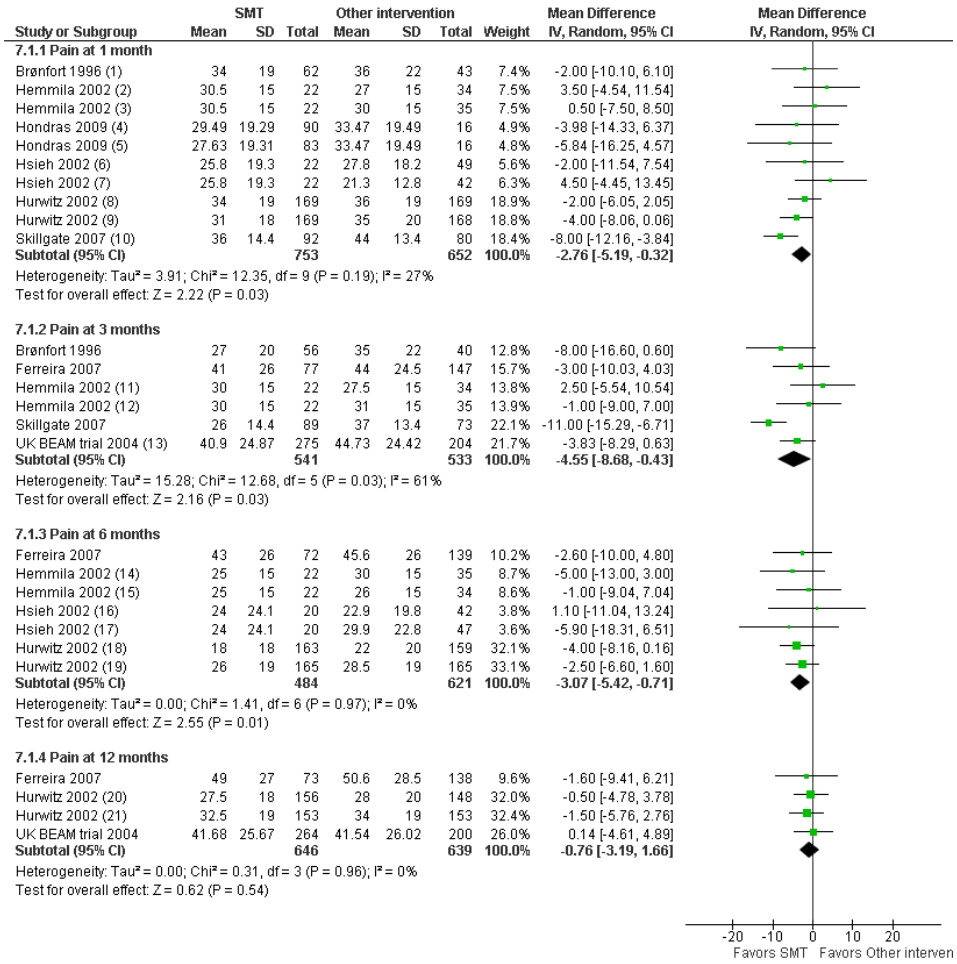
Effect of SMT versus all other interventions

In total, 15 studies (Brønfort 1996; Ferreira 2007; Gibson 1985; Gudavalli 2006; Hemmila 2002; Hondras 2009; Hsieh 2002; Hurwitz 2002; Mohseni-Bandpei 2006; Paatelma 2008; Rasmussen-Barr 2003; Skillgate 2007; UK BEAM trial 2004; Wilkey 2008; Zaproudina 2009) were examined in the meta-analyses, eight with a low RoB. Data from three studies were not included because these data could not be extracted (Koes 1992; Pope 1994; Postacchini 1988), and data from Koes 1992 (low RoB) are described below, where relevant.

For pain and to a lesser extent, functional status, there was substantial heterogeneity for the short-term and intermediate follow-ups Analysis 3.1 and Analysis 3.2); therefore, results are reported separately for these outcomes for only studies with a low RoB. This step was taken because heterogeneity across studies was much less when accounting for risk of bias and far more studies were available for this comparison than any of the other comparisons. Furthermore, there was, at most, a two-point difference in pain (100-point scale, range: 0.13 to 2.01) and at most a 0.13-point difference for functional status (standardized mean difference (SMD), range: 0 to 0.13) for any of the particular time measurements between studies with a low RoB only and all studies; therefore, we feel confident in presenting these stratified results here. In general, the effect was not systematically greater when including all studies as compared to only including studies with a low RoB. In total, eight studies (Brønfort 1996; Ferreira 2007;Hemmila 2002; Hondras 2009; Hsieh 2002; Hurwitz 2002; Skillgate 2007; UK BEAM trial 2004) with a low RoB were examined (Analyses 7.1 to 7.5).

For pain, there is high quality evidence that SMT provides statistically significantly better pain relief than other interventions at one and six months (MD: -2.76, 95% CI: -5.19 to -0.32; MD: -3.07, 95% CI: -5.42 to -0.71, respectively) Figure 5; however, there is also high quality evidence from three studies (Ferreira 2007; Hurwitz 2002; UK BEAM trial 2004) (1,285 participants) that SMT is not statistically more effective for pain relief at 12 months (MD: -0.76, 95% CI: -3.19 to 1.66). At three months, despite substantial heterogeneity from five studies (Brønfort 1996; Ferreira 2007; Hemmila 2002; Skillgate 2007; UK BEAM trial 2004) (1,047 participants), SMT provides significantly better pain relief than the control interventions (MD: -4.55, 95% CI: -8.68 to -0.43; I^2=61%). It is noteworthy that only one of the effect estimates (Hemmila 2002, N = 56) favours the control group in this particular comparison.

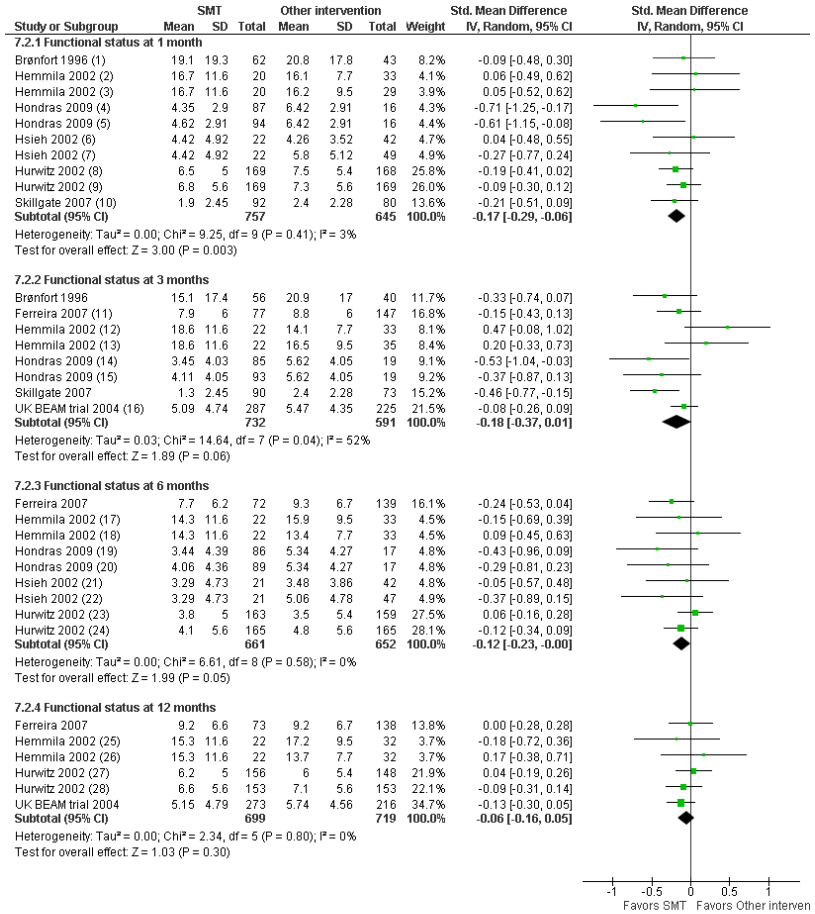
Figure 5. Forest plot of comparison: 7. SMT vs. any other intervention - for studies with a low RoB only, outcome: 7.1 Pain.



(1) HVLA-SMT + strength exercises vs. NSAID + strength exercises;
(2) vs. physiotherapy
(3) vs. exercise
(4) HVLA-SMT vs medical care; adjusted scores from linear effects model; data from author
(5) LVVA-SMT (flexion-distraction) vs. medical care; adjusted scores from linear effects model; data from author
(6) SMT vs. Myofascial therapy
(7) SMT vs. Back school
(8) chiropractic care only vs. medical care only; data from 6 weeks; average pain; data estimated from graphs; SD used from baseline
(9) chiropractic care +physical modalities (DCPm) vs. medical care + physical therapy (MDpt); data from 6 weeks; average pain; data estimated fror
(10) Naprapathy vs. std. medical care; data provided by author
(11) vs physiotherapy
(12) vs exercise
(13) Best care + SMT vs. Best care + exercise
(14) vs exercise
(15) vs physiotherapy
(16) vs. back school
(17) vs. myofascial therapy
(18) physical modalities (DCPm)
(19) vs. medical care only
(20) +physical modalities (DCPm)
(21) vs. medical care only

For functional status, there is high quality evidence that SMT provides statistically significantly better functional improvement at one month compared to other interventions (SMD: -0.17, 95% CI: -0.29 to -0.06). There is moderate quality evidence (inconsistency) of no statistically significant effect at three months (SMD: -0.18, 95% CI: -0.37 to 0.01) and high quality evidence of no statistically significant effect at six and 12 months (SMD: -0.12, 95% CI: -0.23 to 0.00; SMD: -0.06, 95% CI: -0.16 to 0.05, respectively) Figure 6.

Figure 6. Forest plot of comparison: 7. SMT vs. any other intervention - for studies with a low RoB only, outcome: 7.2 Functional status.



(1) HVLA-SMT + strength exercises vs. NSAID + strength exercises; RMDQ
(2) SMT vs. physiotherapy; change scores presented in text; SD's used from baseline; number of SMT subjects was halved; Oswestry.
(3) SMT vs. exercise; change scores presented; SD's used from baseline; number of SMT subjects was halved; Oswestry.
(4) LVVA-SMT (flexion-distraction) vs. medical care; RMDQ; adjusted scores from linear effects model - data from author
(5) HVLA-SMT vs medical care; RMDQ; adjusted scores from linear effects model - data from author
(6) HVLA-SMT vs. back school; RMDQ
(7) HVLA-SMT vs. Myofascial therapy; RMDQ
(8) chiropractic care + physical modalities vs. medical care + physical therapy; data from 6 weeks; RMDQ; data estimated from graphs; SD used fro
(9) chiropractic care only vs. medical care only; data from 6 weeks; RMDQ; data estimated from graphs; SD used from baseline score
(10) Naprapathy vs. std. medical care; data provided by author; CPQ - von Korff scale
(11) SMT vs. general + motor control exercise; RMDQ
(12) vs. physiotherapy
(13) vs. exercise
(14) LVVA-SMT (flexion-distraction) vs. medical care;
(15) HVLA-SMT vs medical care
(16) Best care + SMT vs. Best care + exercise
(17) vs. exercise
(18) vs. physiotherapy
(19) LVVA-SMT (flexion-distraction) vs. medical care
(20) HVLA-SMT vs medical care
(21) vs. back school
(22) vs. myofascial therapy
(23) + physical modalities
(24) vs. medical care only
(25) vs. exercise
(26) vs. physiotherapy
(27) + physical modalities
(28) vs. medical care only

Four studies examined perceived recovery (Gibson 1985; Gudavalli 2006; Hemmila 2002; Zaproudina 2009), one with a low RoB (Hemmila 2002). There is moderate quality evidence (high RoB) from three studies at one month (Gibson 1985; Gudavalli 2006; Hemmila 2002) (370 participants) and low quality evidence (high RoB, imprecision) from two studies (Gibson 1985; Zaproudina 2009) (182 participants) at three months that SMT provides a significantly better chance of recovery than the contrast interventions (RR: 1.20, 95% CI: 1.04 to 1.37; RR: 1.70, 95% CI: 1.20 to 2.40, respectively) (Analysis 3.3). There is also low quality evidence (inconsistency, imprecision) from one study (Hemmila 2002) demonstrating no statistically significant difference in effect on recovery at six or 12 months (RR: 1.05, 95% CI: 0.81 to 1.38; RR: 1.17, 95% CI: 0.87 to 1.55, respectively). The study by Koes 1992 reported significantly ($P < 0.05$) greater improvement for SMT versus standard medical care, but not physiotherapy at six weeks, and no significant difference between either at three months.

Four studies (Brønfort 1996; Gibson 1985; Gudavalli 2006; Hemmila 2002) (596 participants), two of which had a low RoB (Brønfort 1996; Hemmila 2002), examined return-to-work. There is low quality evidence (high RoB, imprecision) that there is no statistically significant effect of SMT on return-to-work at any short or long-term interval (Analysis 3.4). Four studies examined health-related quality of life (Brønfort 1996; Gudavalli 2006; Rasmussen-Barr 2003; Zaproudina 2009) (478 participants), one of which had a low RoB. Based upon these three studies, there is moderate quality evidence (high RoB) at one month demonstrating no statistically significant difference in effect on health-related quality of life (RR: -0.08, 95% CI: -0.29 to 0.13) and very low quality evidence (high RoB, inconsistency, imprecision) of no significant difference in effect at three months (RR: 0.21, 95% CI: -0.27 to 0.70) (Analysis 3.5).

Effect of SMT plus another intervention versus the intervention alone

In total, five studies (Evans 1978; Hsieh 2002; Licciardone 2003; Rasmussen 2008; UK BEAM trial 2004) were identified, two of which had a low RoB (Hsieh 2002; UK BEAM trial 2004). There is low quality evidence (high RoB, imprecision) from three studies (Hsieh 2002; Licciardone 2003; Rasmussen 2008) (228 participants) that SMT has a statistically significant effect on pain relief at one month (MD: -5.88, 95% CI: -10.85 to -0.90) and high quality evidence from two studies (Licciardone 2003; UK BEAM trial 2004) (1,016 participants) that SMT has a statistically significant effect on pain relief at three months (MD: -7.23, 95% CI: -11.72 to -2.74) (Analysis 6.1). There is also high quality evidence from two studies (Rasmussen 2008; UK BEAM trial 2004) (1,000 participants) that SMT has a statistically significant effect on pain relief at 12 months (MD: -3.31, 95% CI: -6.60 to -0.02). However, there is low quality evidence (high RoB, imprecision), which demonstrates no statistically significant difference in effect on pain relief at six months (MD: -6.77, 95% CI: -14.07 to 0.53). Three studies (Hsieh 2002; Licciardone 2003; UK BEAM trial 2004) examined functional status, two of which had a low RoB. There is low quality evidence (high RoB, imprecision) from two studies (156 participants) that SMT has a statistically significant effect on functional status at one month (SMD: -0.40, 95% CI: -0.73 to -0.07) and high quality evidence from two studies (Licciardone 2003; UK BEAM trial 2004) at three months (1,078 participants) that SMT has a statistically significant effect on functional status (SMD: -0.22, 95% CI: -0.38 to -0.06) and a statistically significant effect at 12 months (SMD: -0.21, 95% CI: -0.34 to -0.09). However, there is low quality evidence (high RoB, imprecision) that SMT has no statistically significant effect at six months (SMD: -0.30, 95% CI -0.64 to 0.03) (Analysis 6.2).

One study with a high RoB examined perceived recovery (Evans 1978). There is very low quality evidence (high RoB, inconsistency, imprecision) that SMT demonstrates significantly greater recovery at one month than the comparison group (RR: 3.40, 95% CI: 1.12 to 10.28) (Analysis 6.3). No data were available on return-to-work or health-related quality of life.

Sensitivity analyses

Sensitivity analyses were conducted for the comparison SMT *versus* all other interventions only. Only two outcomes were examined, pain and functional status. The sparseness of data for the other comparisons rendered further sub-analyses meaningless. These analyses were conducted in order to determine the robustness of our original analyses and determine whether other factors might have influenced the overall pooled effect.

On the basis of these sensitivity analyses, results appear more prominently for those studies with a low RoB because heterogeneity across studies was much less than when all studies were pooled; however, the overall pooled effect between all studies and those with a low RoB were only marginally different for pain and functional status at all time measurements (Figure 7; Figure 8). It is noteworthy that a small difference in effect was observed for SMT *versus* interventions thought to be ineffective as opposed to SMT *versus* interventions thought to be effective; however, this amounted to a difference of at most, five points on a 100-point scale (Figure 7, Summary Forest plot - pain at 1 month) or 0.3 points in SMD (Figure 8, Summary Forest Plot - functional status at 1 month). However, none of these analyses suggested a clinically-relevant effect on pain or functional status at any time interval not observed in the primary analyses. Furthermore, with the exception of two studies (Wilkey 2008; Evans 1978), both with a

high RoB, no other study demonstrated a clinically-relevant effect for any comparison or time interval for the primary outcomes, pain, functional status or perceived recovery. The sensitivity analyses were less remarkable at the remaining time intervals and are available upon request from the contact author.

Figure 7. Summary forest plot as part of the sensitivity analyses. Comparison: SMT vs. all other interventions. Outcome: Pain at one month.

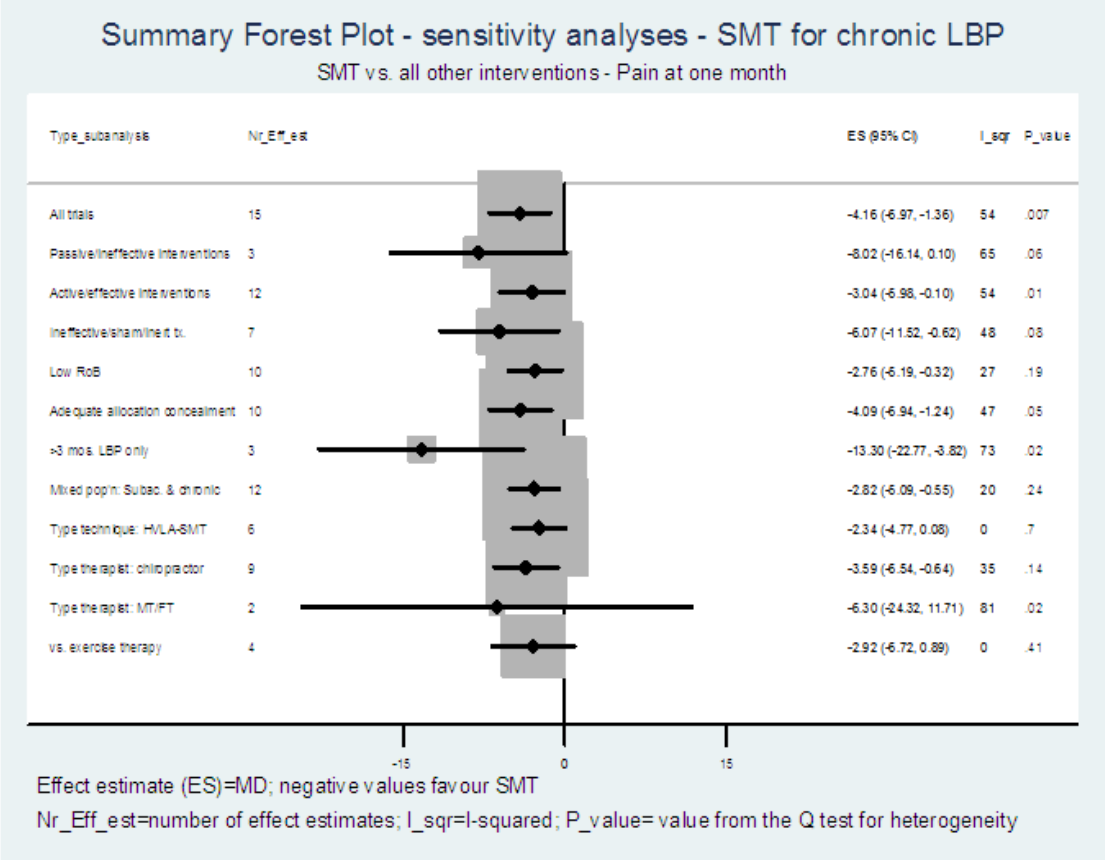
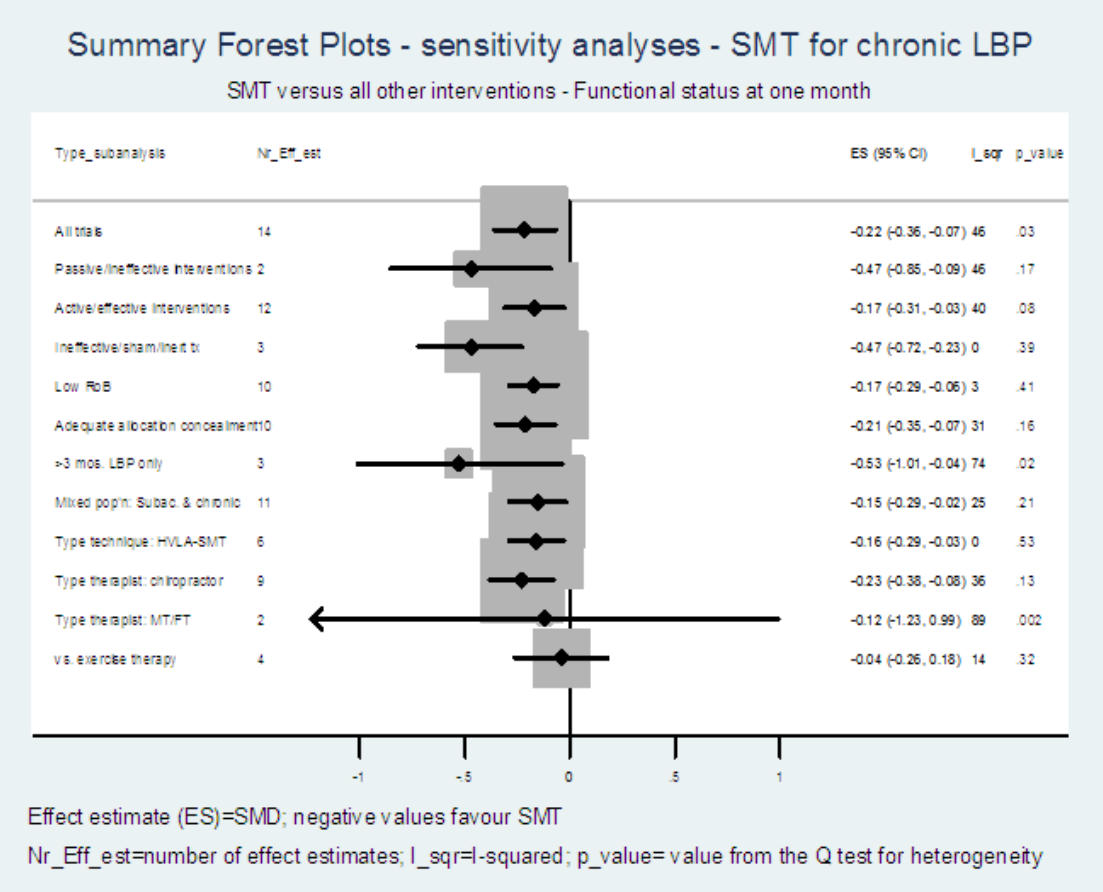


Figure 8. Summary forest plot as part of the sensitivity analyses. Comparison: SMT vs. all other interventions. Outcome: Functional status at one month.



We wanted to examine the effect of SMT in subjects with radiating pain; however, most studies included subjects with or without radiating pain and did not present separate analyses, so this sensitivity analysis was not performed. Finally, while it was not part of the original sensitivity analysis, lowering the threshold value for I^2 to 40% would not have had any bearing on the presentation of these results.

ADDITIONAL SUMMARY OF FINDINGS *[Explanation]*

spinal manipulative therapy (SMT) compared to sham SMT for chronic LBP

Patient or population: patients with chronic LBP
Settings: Rather diverse
Intervention: spinal manipulative therapy (SMT)
Comparison: sham SMT

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	sham SMT	spinal manipulative therapy (SMT)				
Pain VAS. Scale from: 0-100 (worse pain). Follow-up 1 month	The mean pain ranged across control groups from **31 to 58 points**	The mean Pain in the intervention groups was **3.24 lower** (13.62 lower to 7.15 higher)		148 (3 studies)	⊕○○○ **very low**[1,2,3,4,5]	
Pain VAS. Scale from: 0-100 (worse pain). Follow-up: 3 months	The mean pain in the control groups was **28.5 points**	The mean Pain in the intervention groups was **2.50 higher** (9.64 lower to 14.64 higher)		55 (1 study)	⊕○○○ **very low**[1,3,4,5]	
Pain VAS. Scale from: 0-100 (worse pain). Follow-up: 6 months	The mean pain in the control groups was **24.5 points**	The mean Pain in the intervention groups was **7.10 higher** (5.16 lower to 19.36 higher)		51 (1 study)	⊕○○○ **very low**[1,3,4,5]	

Functional status Roland Morris Disability Questionnaire. Scale from 0 to 24 (worse function). Follow-up: 1 month	The mean functional status in the control groups was **7.7**	The mean Functional status in the intervention groups was **2.16 lower** (4.65 lower to 0.29 higher)		65 (1 study)	⊕○○○ **very low**[1,3,4,6]	Based on SMD: -0.45 (-0.97 to 0.06). Strength of the effect is small
Functional status Roland Morris Disability Questionnaire. Scale from: 0 to 24 (worse function). Follow-up: 3 months	The mean functional status in the control groups was **6.1**	The mean Functional status in the intervention groups was **0.00 higher** (2.3 lower to 2.3 higher)		55 (1 study)	⊕○○○ **very low**[1,3,4,6]	Based on SMD: 0.00 (-0.56 to 0.56). No effect.
Functional status Roland Morris Disability Questionnaire. Scale from: 0 to 24 (worse function). Follow-up: 6 months	The mean functional status in the control groups was **5**	The mean Functional status in the intervention groups was **0.18 higher** (2.34 lower to 2.75 higher)		51 (1 study)	⊕○○○ **very low**[1,3,4,6]	Based on SMD: 0.04 (-0.52 to 0.61). Strength of the effect is small

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] >25% of participants from studies with a high risk of bias
[2] I-squared=53%
[3] Licciardone et al. included relatively inexperienced osteopathic manipulative physicians.
[4] Less than 400 subjects, total.
[5] Effect includes the possibility of better or worse pain relief with SMT.
[6] Effect includes the possibility of better or worse function with SMT.

Spinal manipulative therapy compared to all other interventions for chronic low-back pain

Patient or population: patients with chronic low-back pain
Settings: Rather diverse
Intervention: spinal manipulative therapy
Comparison: all other interventions

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk all other interventions	Corresponding risk spinal manipulative therapy				
Pain VAS. Scale from: 0-100 (worse pain). Follow-up: 1 month	The mean pain ranged across control groups from **21.3 to 44 points**	The mean Pain in the intervention groups was **2.76 lower** (5.19 to 0.32 lower)		1405 (6 studies[1])	⊕⊕⊕⊕ **high**	
Pain VAS. Scale from: 0-100 (worse pain). Follow-up: 3 months	The mean pain ranged across control groups from **27.5 to 44.7 points**	The mean Pain in the intervention groups was **4.55 lower** (8.68 to 0.43 lower)		1074 (5 studies[1])	⊕⊕⊕○ **moderate**[2]	
Pain VAS. Scale from: 0-100 (worse pain). Follow-up: 12 months	The mean pain ranged across control groups from **28 to 50.6 points**	The mean Pain in the intervention groups was **0.76 lower** (3.19 lower to 1.66 higher)		1285 (3 studies[1])	⊕⊕⊕⊕ **high**[3]	
Functional status Roland Morris Disability Questionnaire. Scale from: 0 to 24 (worse function). Follow-up: 1 month	The mean functional status ranged across control groups from **4 to 20.8**	The mean Functional status in the intervention groups was **0.9 lower** (1.6 to 0.3 lower)		1402 (6 studies[1])	⊕⊕⊕⊕ **high**	Based on SMD: -0.17 (-0.29 to -0.06). Strength of the effect is small

Functional status Roland Morris Disability Questionnaire. Scale from: 0 to 24 (worse function). Follow-up: 3 months	The mean functional status ranged across control groups from **6 to 20.9**	The mean Functional status in the intervention groups was **0.74 lower** (1.5 lower to 0.04 higher)		1323 (6 studies[1])	⊕⊕⊕○ **moderate**[4]	Based on SMD: -0.18 (-0.37 to 0.01). Strength of the effect is small
Functional status Roland Morris Disability Questionnaire. Scale from 0 to 24 (worse function). Follow-up: 12 months	The mean functional status ranged across control groups from **5.7 to 9.2**	The mean Functional status in the intervention groups was **0.32 lower** (0.86 lower to 0.27 higher)		1418 (4 studies[1])	⊕⊕⊕⊕ **high**[5]	Based on SMD: -0.06 (-0.16 to 0.05). Strength of the effect is small
Recovery at 1 month	**Study population**		**RR 1.20** (1.04 to 1.37)	370 (3 studies)	⊕⊕⊕○ **moderate**[6]	
	598 per 1000	**718 per 1000** (622 to 819)				
	Medium risk population					

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Results based upon studies with a low risk of bias.
[2] I-squared=61%
[3] Effect includes the possibility of better or worse pain relief with SMT.
[4] I-squared=52% and widely varying effect estimates in favor of either SMT or the intervention.
[5] Effect includes the possibility of better or worse function with SMT.

[6] >25% of participants from studies with a high risk of bias

spinal manipulative therapy plus any intervention compared to the intervention alone for chronic LBP

Patient or population: patients with chronic LBP
Settings: Rather diverse
Intervention: spinal manipulative therapy plus any intervention
Comparison: the intervention alone

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	the intervention alone	spinal manipulative therapy plus any intervention				
Pain VAS. Scale from: 0-100 (worse pain). Follow-up: 1 month	The mean pain ranged across control groups from **27.8 to 46.5 points**	The mean Pain in the intervention groups was **5.88 lower** (10.85 to 0.9 lower)		228 (3 studies)	⊕⊕◯◯ **low**[1,2]	
Pain VAS. Scale from: 0-100 (worse pain). Follow-up: 3 months	The mean pain ranged across control groups from **45.2 to 49.6 points**	The mean Pain in the intervention groups was **7.23 lower** (11.72 to 2.74 lower)		1016 (2 studies)	⊕⊕⊕⊕ **high**	
Pain VAS. Scale from: 0-100 (worse pain). Follow-up: 12 months	The mean pain ranged across control groups from **20 to 47.6 points**	The mean Pain in the intervention groups was **3.31 lower** (6.6 to 0.02 lower)		1000 (2 studies)	⊕⊕⊕⊕ **high**	
Functional status Roland Morris Disability Questionnaire. Scale from: 0 to 24 (worse function). Follow-up: 1 month	The mean functional status ranged across control groups from **5.8 to 6.9**	The mean Functional status in the intervention groups was **2.05 lower** (3.73 to 0.36 lower)		156 (2 studies)	⊕⊕◯◯ **low**[1,2]	Based on SMD: -0.40 (-0.73 to -0.07). Strength of the effect is small

Functional status Roland Morris Disability Questionnaire. Scale from: 0 to 24 (worse function) . Follow-up: 3 months	The mean functional status ranged across control groups from **5.5 to 6.7**	The mean Functional status in the intervention groups was **1.06 lower** (1.82 to 0.29 lower)		1078 (2 studies)	⊕⊕⊕⊕ **high**	Based on SMD: -0.22 (-0.38 to -0.06). Strength of the effect is small
Functional status Roland Morris Disability Questionnaire. Scale from: 0 to 24 (worse function). Follow-up: 12 months	The mean functional status ranged across control groups from **5.7 to 6.2**	The mean Functional status in the intervention groups was **0.97 lower** (1.56 to 0.41 lower)		994 (1 study)	⊕⊕⊕⊕ **high**	Based on SMD -0.21 (-0.34 to -0.09). Strength of the effect is small
Recovery at one month	**Study population**		**RR 3.40** (1.12 to 10.28)	32 (1 study)	⊕◯◯◯ **very low**[1,3]	
	176 per 1000	**598 per 1000** (197 to 1000)				
	Medium risk population					

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] >25% of participants from studies with a high risk of bias
[2] Less than 400 subjects, total.
[3] Less than 300 subjects, total.

DISCUSSION

Summary of main results

In general, there is high quality evidence that SMT has a statistically significant short-term effect on pain relief and functional status compared to other interventions as well as varying quality of the evidence that SMT has a statistically significant short-term effect on pain relief and functional status when SMT is added to another intervention. However, the size of the effects were small and not apparently clinically relevant. In addition, there is very low quality evidence that SMT is no more effective than inert interventions or sham SMT for short-term pain relief or functional status. Seemingly these results are conflicting. This might be explained by the fact that relatively few, small studies, quite typically with a high RoB, evaluated the latter comparisons, thus, these studies have a high likelihood of a type II error stemming from the low power of the study to detect a statistically significant and clinically relevant effect. However, studies with a high RoB typically overestimate the effect compared to studies with a low RoB (van Tulder 2009), so it is unclear to what extent, if any, various forms of bias have on those results. Furthermore, it is questionable to what extent studies investigating sham SMT were able to successfully blind their subjects as only one study evaluated this post-treatment, suggesting that perhaps the investigators were partially successful, although it is debatable whether these data can be considered representative for this comparison. Nevertheless, improper blinding is likely to have lead to an overestimation of the effect, not underestimation, thus, it is also difficult to interpret the essence of these findings in relation to our more robust comparison, SMT versus other interventions. Data were particularly sparse for recovery, return-to-work and quality of life, in addition to costs of care; therefore, no firm conclusions can be drawn regarding these outcomes.

Recently, there has been much discussion regarding the clinical importance of small effects identified in continuous outcomes, such as those examined in this review. Formerly, it was thought that the effect of a treatment was trivial if the mean difference between the treatment and a control group was appreciably less than the smallest change thought to be clinically important. This might not necessarily be so (Guyatt 1998). The addition of the number needed to treat (NNT) may aid interpretation of trials with continuous outcomes (Froud 2009), especially when expressed as a standardized mean difference. For example, the largest benefit demonstrated from any of the treatments in the UK BEAM (2004) trial was 1.87 points on the Roland-Morris disability questionnaire, which translates to a between-group difference that is not clinically important (Tveito 2005). A recent re-analysis of these data suggests that despite the small mean differences between interventions, numbers needed to treat were small, on average, four to five for manipulation plus exercise or manipulation alone, respectively as compared to "best care" at three months follow-up (Froud 2009). This means that referring four to five patients for manipulation, would, on average, yield one additional case of improvement. Even a conservative estimate with these data suggests a potentially attractive NNT ratio. However, it should be noted that this represents a *post-hoc* analysis and there are some general limitations to the use of NNT analyses (Wu 2001). Furthermore, calculation of a NNT is based upon determination of a threshold value of improvement, which is also open for discussion. Finally, statistical power is lost when converting scales to binary outcomes; therefore, this technique might only be attractive when sample sizes are sufficiently large (Guyatt 1998).

Despite the methodological rigor maintained in this review, there are likely to be objections. One objection typically raised by clinicians is the lack of respect to the type of manipulative therapy delivered (e.g. high-velocity low-amplitude manipulation *versus* mobilization) or profession of the therapist (e.g. chiropractor *versus* manual therapist or physiotherapist). Sensitivity analyses were conducted in order to distinguish whether this resulted in a different effect; however, those results suggest that neither the technique nor profession of the therapist had a profound influence on the overall pooled effect.

Another objection might lie with the lack of examining a more homogenous group of subjects with low-back pain. Non-specific low-back pain, even when examined by duration, can probably be viewed as a rather heterogenous group. Even within this review, a number of studies included subjects with and without radiating pain; therefore, defining a homogenous population and identifying subgroups seems important. Recent work suggests that clinically important effects are observed when treatment is matched to the patient's signs and symptoms rather than provided to all patients with low-back pain (Brennan 2006). Furthermore, recent recommendations from a UK consensus, which included senior researchers experienced in clinical trials for musculoskeletal conditions, include examining subgroups (Foster 2009).

None of the included studies which examined adverse events reported serious complications. Serious complications following SMT for low-back pain are extremely rare and have been documented in case reports only, which include cauda equina syndrome (CES), paraplegia and death (Cherkin 2003). Risk estimates vary widely for CES, ranging from less than one case per million treatments (Assendelft 1996) to one case per 100 million manipulations (Shekelle 1992). Given the extremely low incidence of serious complications, a review of RCTs provides limited information; however, estimates based upon case reports are likely to underestimate risk, while large prospective cohorts are lacking. To our knowledge, only one systematic review has examined the safety of SMT to the low-back based upon case reports and surveys, which concluded that the risk of SMTcausing a clinically worsened disc herniation or CES in a patient presenting with lumbar disc herniation to be estimated at one in 3.7 million treatments (Oliphant 2004).

Limitations and strengths

There are a number of limitations to this review. The primary limitation, which is common to many systematic reviews, is the

lack of studies with a low RoB. Despite the fact that the majority of the studies included in this review were published in the last decade, methodologically well conducted studies remain scarce.
A second limitation is the possibility of publication bias, which we attempted to minimize through an extensive database search. We did not actively seek unpublished studies; however, it could be argued that this is unlikely to have had an important impact on the overall results. Suprisingly, many of the studies published in the last decade did not have a published protocol and to our knowledge, had not registered their study in one of the many trial registries, indicating that many trials conducted in the 21st century still do not conform to international procedure. In the absence of 100% conformity, it remains difficult to ascertain to what extent studies do not publish their findings because the results prove less than favourable. In addition, we uncovered a couple of irregularities, for example, a study that began recruitment ten years ago, but has not yet been published (ISRCTN61808774) or another study that was terminated without further explanation (NCT00269503).
Finally, we would have liked to have conducted a meta-regression for the purpose of exploring heterogeneity between studies; however, there were too few studies per outcome to allow for a meaningful analysis and the distribution of data for the outcomes, pain and functional status, appeared to be clustered, that is, the data did not follow a normal distribution. Furthermore, results from the sensitivity analyses did not suggest any important directions of effect for the confounders and effect modifiers examined.
Strengths of this review include the methodological rigor applied, including a published protocol and the meta-analyses, which allowed us to conduct meaningful sensitivity analyses.

Agreements and disagreements with other studies or reviews

Ostensibly, these results are consistent with the previous review, which concluded that there is evidence that SMT is neither superior nor inferior to other effective treatments for patients with chronic low-back pain. In comparison to the previous review (Assendelft 2003; Assendelft 2004), approximately two-thirds of the studies included are new and many more studies have been included with a low RoB; therefore, our findings are thought to be much more robust. These results are also consistent with other recent systematic reviews, which conducted principally narrative analyses (Brønfort 2008; Chou 2007; Lawrence 2008); however, the findings from our review are more optimistic than another review (Ferreira 2002), which conducted meta-analyses. Another systematic review was identified which pooled data from six trials of osteopathic manipulative therapy (OMT) and concluded that OMT significantly reduces low-back pain (Licciardone 2005); however, that review did not limit the results to trials of chronic low-back pain. A recent review of systematic reviews, including the earlier version of this review, concluded that SMT produces small clinical benefits that are equivalent to those of other commonly used therapies (Cherkin 2003).

AUTHORS' CONCLUSIONS

Implications for practice

High quality evidence suggests that there is no clinically relevant difference between SMT and other interventions for reducing pain and improving function in patients with chronic low-back pain. Therefore, the decision to refer for SMT should be based upon costs, preferences of the patient and providers and relative safety of the treatment options.

Implications for research

Future studies should:

1. Evaluate the effects of SMT as an additional or adjunct therapy, for example, in the case of SMT in multi-modal treatment packages.

2. There is a dire need for cost-effectiveness studies. If SMT is equal to other presumed effective interventions for chronic low-back pain, SMT may be more cost-effective because the therapy is typically provided in a limited number of treatment sessions (as compared to, for example, exercise therapy or behavioural treatment).

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ISRCTN61808774 *{published data only}*

A randomised controlled trial of the effect on chronic low-back pain of a naturopathic osteopathy intervention. Ongoing study April 2000; recruitment completed; information last updated Nov. 2005.

NCT00269321 *{published data only}*

randomised clinical trial of chiropractic manual therapy plus home exercise, supervised exercise plus home exercise and home exercises alone for individuals 65 and over with chronic mechanical low-back painPrimary aims: to determine the relative clinical effectiveness the following treatments for LBP patients 65 years and older in both the short-term (after 12 weeks) and long-term (after 52 weeks), using LBP as the main outcome measure.Secondary outcomes: to estimate the short- and long-term relative effectiveness of the three interventions using:Patient-rated outcomes: low-back disability, general health status, patient satisfaction, improvement, and medication use measured by self-report questionnairesObjective functional performance outcomes: spinal motion, trunk strength and endurance, and functional ability measured by examiners masked to treatment group assignmentCost measures: direct and indirect costs of treatment measured by questionnaires, phone interviews, and medical records.To describe elderly LBP patients' perceptions of treatment and the issues they consider when determining their satisfaction with care using qualitative methods nested within the RCT.. Ongoing study October 2003; recruitment completed as of June 2008..

NCT00269347 *{published data only}*

Title: Manipulation, exercise and self-care for non-acute low-back painBuilding upon the principal investigators' previous collaborative research, this randomised observer-blinded clinical trial will compare the following treatment for patients with non-acute low-back pain:chiropractic spinal manipulationrehabilitative exerciseself care education Theprimary aim is to examine the relative efficacy of the three interventions in terms of patient rated outcomes in the short-term (after 12 weeks) and the long-term (after 52 weeks) for non-acute low-back pain.Secondary aims include:To examine the short and long-term relative cost effectiveness and cost utility of the three treatments.To assess if there are clinically important differences between pre-specified subgroups of low-back pain patients. Subgroups are based on duration and current episode and radiating leg pain.To evaluate if there treatment group differences in objective lumbar spine function (range of motion, strength and endurance) after 12 weeks of treatment and if changes in lumbar function are associated with changes in patient rated short and long-term outcomes.To identify if baseline demographic or clinical variables can predict short or long-term outcome.To describe patients' interpretations and perceptions of outcome measures used in clinical trials. Ongoing study January 2001; recruitment completed as of June 2008; currently in the review process..

NCT00269503 *{published data only}*

Official title: A Pilot Study of Chiropractic Prone Distraction for Subacute Back Pain With Sciatica. Ongoing study Starting date of trial not provided. Contact author for more information.

NCT00315120 *{published data only}*

A randomised controlled trial of osteopathic manipulative treatment and ultrasound physical therapy for chronic low-back pain. Ongoing study August 2006; estimated study completion date: June 2010.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Brønfort 1996

Methods	RCT; Adequate allocation procedure; randomisation ratio = 3:2:2
Participants	174 patients randomly allocated to 3 treatment groups; study setting: chiropractic outpatient clinic; patients recruited from local advertisements in newspaper; study conducted in Minneapolis/St. Paul, Minnesota, USA; recruitment September 1991- May 1993 Age (mean (SD): Overall: 41.0 (9.7); grp.1- 41.3 (10.5); grp.2 - 40.3 (8.9); grp.3 - 41.4 (9.3) Gender (% F): Overall: 47%; grp.1 - 54%; grp.2 - 44%; grp.3 -39% Inclusion criteria: subjects between 20 to 60 years of age with non-specific LBP of at least 6 weeks duration with or without radiating pain to one or both legs to the level of the knee Duration of the current episode: range 2 to 3 years (median) for all 3 groups Exclusion criteria: subjects with LBP caused by specific identifiable pathology in the spine and lower extremities: organic diseases with referred pain to the lumbar spine; severe osteopenia; previous back surgery; severe arterial hypertension or existing cardiovascular diseases requiring medical treatment; poor general health; obesity; history of duodenal or stomach ulcers; previous hypersensitivity to NSAIDs; pregnancy; pending litigation; and difficulties with the English language
Interventions	1) SMT + strengthening exercises (N = 71); 2) NSAIDs + strengthening exercises (N = 52); 3) SMT + stretching exercises (N = 51) SMT: Treatments provided by 5 licensed chiropractors whose practice experience varied from 5 to 25 years. A total of 10 tx. sessions were provided, all during the first 5 wks. of the trial, each lasting 5 to 10 min. The choice of tx. technique was at the discretion of the chiropractor. No adjunctive physiotherapy was allowed. The thrusting technique was a high-velocity, low-amplitude thrust, most commonly by a short-lever technique Pharmaceutical therapy: Naproxen (500 mg.), twice daily; no other prescription NSAIDs or analgesics were allowed Exercise protocol: Research assistants specifically trained and certified by the principal investigator supervised all 20 exercise sessions. During the first 5 weeks of tx., 10 exercise sessions were done in combination w/ either SMT or the NSAID intervention. For the subsequent 6 wks., patients came solely for the 10 supervised sessions. The dynamic trunk strengthening protocol consisted of trunk and leg extensions as described by Manniche (ref.21). At the completion of the study, all patients were encouraged to continue with their exercises The 11-week treatment protocol for all 3 groups consisted of 5 weeks of combination therapy followed by 6 weeks of exercise therapy alone, totaling 20 1-hour sessions
Outcomes	Primary outcomes (as defined by the authors): Pain: NRS (11-point ordinal scale); Back pain-specific functional status: Roland-Morris; Generic functional status: COOP-WONCA; Secondary outcomes: Depression: Community Epidemiologic Scale Depres-

Brønfort 1996 (*Continued*)

	sion (developed by the National Institutes of Health); Trunk performance tests (trunk muscle strength, endurance, and range of motion as measured by a computerized digital myograph, Schober's test, straight leg raise test, and time the subjects were able to maintain their upper body horizontally unsupported) Not reported as a primary or secondary outcome in the methods, but results are presented for the following: percentage of patients achieving a given percentage reduction in pain; return-to-work; adverse events adverse events: 2 subjects developed severe nausea & vomiting but not gastrointestinal bleeding due to the NSAID use and subsequently discontinued the study; 8 subjects developed substantial nausea & dyspepsia and 1 subject severe tinnitus following NSAID use; 1 subject discontinued exercise because she did not tolerate it well and 7 subjects developed muscle soreness & stiffness, including neck pain following exercise - these symptoms gradually abated and did not prevent them from completing the study; 1 subject developed symptoms of a myocardial infarction unrelated to exercise Follow-up: 5 & 11 weeks, 1 year
Notes	Authors results and conclusions: Individual group comparisons after 5 & 11 wks. of intervention on all 3 main outcome measures did not reveal any clear clinically important or statistically significant differences. Continuance of exercise during the follow-up year, regardless of type, was associated with a better outcome. For the management of chronic LBP, trunk exercise in combination with SMT or NSAID therapy seemed to be beneficial and worthwhile Funded by Foundation for Chiropractic Education and Research

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random group assignments drawn from sealed opaque envelopes.
Allocation concealment (selection bias)	Low risk	The allocation process was verified by an independent, professional agent. Comment: No other information was provided
Blinding (performance bias and detection bias) All outcomes - patients	High risk	There is no mention of attempts to blind the patients to other interventions or their perceptions of potential effectiveness of the different interventions
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". Below includes the authors attempt at blinding the "outcomes assessor" "All primary outcome measures were pa-

Brønfort 1996 (*Continued*)

		tient-rated and the trunk performance and range of motion data were obtained by study-certified clinicians blind to group allocation."
Incomplete outcome data (attrition bias) All outcomes - drop-outs	High risk	At 5 wks (% retained): grp.1 - 87% (62/71); grp.2 - 85% (44/52); grp.3 - 82% (42/51) At 11 wks: grp.1 - 79% (56/71); grp.2 - 77% (40/52); grp.3 - 71% (36/51) At 1 year: overall: 72% (not presented for the individual grps.)
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Low risk	
Selective reporting (reporting bias)	High risk	No published protocol was available; recovery not reported. The following were not reported as a primary or secondary outcome, but reported in the results: percentage of patients achieving a given percentage reduction in pain; return-to-work; side effects
Group similarity at baseline	Low risk	
Influence of co-interventions	Low risk	Two patients sought non-study treatment for LBP during the study period
Compliance with interventions	Low risk	Except for the drop-outs, all patients had a better than 85% compliance rate with medication, SMT sessions and exercise sessions during the 3 months of the study
Timing of outcome assessments	Low risk	

Chown 2008

Methods	RCT; unclear allocation treatment assignment
Participants	239 patients randomly allocated to 3 treatment groups; setting: physiotherapy department at one hospital in the United Kingdom; patients referred by the GP or hospital consultant; recruitment period not stated Age (mean (SD)): grp.1 - 44.3 (12.3); grp.2 - 43.5 (12.3); grp.3 - 42.5 (11.9) Gender (% F): grp.1 - 62%; grp.2 - 57%; grp.3 - 55% Inclusion criteria: > 3 months of "simple" LBP of musculoskeletal origin, without sciatic symptoms, 18 to 65 years of age Duration current episode LBP: not stated, but > 3 months for the population

	Exclusion criteria: > 65 years, serious spinal disorders (e.g. malignancy, osteoporosis, ankylosing spondylitis), main complaint of pain below the hip, previous spinal surgery, additional over-riding musculoskeletal disorder, attendance or referral to a specialised management clinic, medical condition (e.g. cardiovascular disease), anticoagulant treatment, steroid medication, unable to get up from or down to the floor unaided, physical therapy (including. acupuncture) in the previous 3 months
Interventions	1) Physiotherapy (N = 80): consisting of education/advice; joint mobilization; soft-tissue mobilisation; McKenzie therapy; neural tension; manual traction; muscle imbalance; postural correction; isometric stabilisation exercises; global exercise for mobility (+ electrotherapy) 2) Osteopathy (N = 79): consisting of soft-tissue massage; soft-tissue inhibition; soft-tissue stretch muscle energy; articulation; high velocity thrust manipulation; functional corrections; exercise advice; education; discussion of psychosocial issues; nutrition/dietary advice. 3) Group exercise with a physiotherapist (N = 80): consisting of problem identification; basic pathophysiology, anatomy, mechanics; home stretching exercise programme; basic postural setting use of transversus/multifidus; question and answer session; re-assessment of subjective and objective markers Patients in each group were required to attend 5 tx. sessions within a 3-month period. Each session was approximately. 30 min. in duration and the format of care was standardized as far as possible
Outcomes	Pain: not reported; Back-pain specific functional status: Oswestry; Quality of Life: EuroQol EQ-5D; shuttle walk test; satisfaction with the intervention received, satisfaction with life; recovery - not reported; adverse events - not reported; comment: Outcomes not defined by the authors as primary or secondary Follow-up: 6 weeks after discharge and 12 months.
Notes	Therapists were allowed to choose from the modalities listed above (identified in Table 1 of the article); Group therapy had the worst attendance - with only 40% of the patients completing all therapy sessions, as compared to 74% for the physiotherapy group and 80% for the osteopathy group; major limitations include problems with recruitment and retention of the sample Authors results and conclusions: All 3 treatments indicated comparable reductions in mean functional status (Oswestry). Attendance rates were significantly lower among the group exercise patients. One-on-one therapies provide evidence of greater patient satisfaction. The study supports the use of a variety of approaches for treatment of chronic low-back pain, but particular attention needs to be given to problems associated with attracting enough participants for group sessions Funded by St. Albans and Hemel Hempstead NHS Trust Research and Development Consortium

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Random sequence generation (selection bias)	Low risk	Patients were assigned at random to one of the three therapy regimes by an independent administrator, using block randomisation methods to ensure approximately equal allocation of patients to each treatment. Random number sequences were generated from random number tables
Allocation concealment (selection bias)	Unclear risk	Eligible patients were allocated at random to one of three therapy regimes: group exercise; physiotherapy; or osteopathy. Note: No other details were offered as to how this was performed or by who
Blinding (performance bias and detection bias) All outcomes - patients	High risk	It is not clear if attempts were made to blind patients to the other interventions or their perceptions of potential effectiveness of those different interventions
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". Below includes the authors attempt at blinding the "outcomes assessor" "Where feasible, individuals involved in the conduct and analysis of the study were blind to either group membership and/or baseline assessments. All follow-up assessments were undertaken by an independent assessor who was blind to baseline measurements and group allocation." (Comment: Attempted blinding would have been limited to assessment and not actual delivery of care.)
Incomplete outcome data (attrition bias) All outcomes - drop-outs	High risk	The numbers and percentages completing the therapy regime by group are stated in Table 3. Group therapy had the worst attendance, with only 40% of patients completing all therapy sessions, compared with 74% within physiotherapy and 80% within osteopathy
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Unclear risk	No mention of an ITT analysis; however, the authors might have chosen not to conduct this given the large percentage of drop-

Chown 2008 (*Continued*)

		outs at the first follow-up measurement (6 weeks)
Selective reporting (reporting bias)	High risk	Functional status was the only primary outcome reported.
Group similarity at baseline	Low risk	
Influence of co-interventions	Unclear risk	Not stated.
Compliance with interventions	High risk	In addition to the above item: Investigation of the reasons for non-completion (Table 4 in article) reveals that the high dropout rate of patients allocated to group exercise is largely attributable to problems with waiting and appointment times. Individuals who did not attend a session and did not subsequently contact the department were discharged, as local policy dictates. The 16 'other reasons' included six patients where further problems were identified, six patients who were unable to complete the course, two patients who received more than six treatment sessions, and one patient who was expecting surgery
Timing of outcome assessments	Low risk	

Evans 1978

Methods	RCT; treatment allocation unclear; Crossover design - consisting of 2 three-week periods
Participants	36 participants randomly allocated to 2 treatment groups; setting: outpatient department?; participants referred from rheumatological and orthopaedic colleagues; conducted in the UK; period or time of recruitment not presented Age: Overall: 25 to 63 years (median - 44.5 years) Gender (% F): Overall: 53% (17/32) Inclusion criteria: back pain > 3 weeks, arising from the inferior angles of the scapulae to the lower sacrum; subjects with femoral or sciatic radiation were allowed. Use of physiotherapy, surgical corsets, NSAIDs or similar interventions were allowed up to the screening examination (1 week prior to beginning the study), but the use of various analgesics (excluding NSAIDs?) was allowed up to entry into the trial (day 1) Duration of the back pain ranged from 0.2 to 31 years (median 4 years), and the current attack had been present for 1 1/2 months to 156 months (median 9 months) Exclusion criteria: subjects with femoral or sciatic nerve root compression signs; use of NSAIDs in the previous 2 months; spondylitis, inflammatory polyarthritis and any overt chronic diseases or psychiatric conditions

Evans 1978 (*Continued*)

Interventions	1) Manipulation (N = 15): delivered by an experienced medically qualified manipulator using rotational thrust with distraction to both sides; 3 times on weekly interval. No other information was provided. 2) "No treatment" (N = 17): consisting of analgesics. First tx. phase consisted of SMT + analgesic (codeine phosphate (2 caps of 16 mg.)) *versus* codeine phosphate alone. After the three week phase, the treatment groups were reversed. Standardized co-intervention: codeine phosphate
Outcomes	Pain (4-point scale: none, mild, moderate, severe); lumbar spine flexion (according to the method of Macrae and Wright); analgesic consumption (number of codeine capsules consumed); patient's assessment of efficacy at the end of the 3-wk. period (4-point scale: ineffective, equivocal, effective, highly effective); patient's preference at the end of the trial; global assessment (4-point scale: deteriorated, no change, slight improvement, marked improvement); adverse events - reported; comment: Outcomes not defined by the authors as primary or secondary adverse events: There were no side-effects in the control or manipulative treatment periods except one patient who complained of constipation after having consumed 24 codeine phosphate capsules in the first 4 days. Follow-up: up to 6 weeks
Notes	Authors results and conclusions: Pain scores were reduced to a significant degree within 4 wks. of starting treatment in the grp. undergoing manipulation during the first treatment period Funded by: Unclear. The authors worked in various departments. in the UK (Dept. of rheumatology; Dept. of diagnostic radiology)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Patients were allocated according to a random list into two groups. (A & B)
Allocation concealment (selection bias)	Unclear risk	Note: No other information was provided on the randomisation procedure or allocation
Blinding (performance bias and detection bias) All outcomes - patients	High risk	There is no mention of attempts to blind the patients to other interventions or their perceptions of potential effectiveness of the different interventions
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups

Evans 1978 (*Continued*)

Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". No mention of trying to blind any outcome assessors involved in the study
Incomplete outcome data (attrition bias) All outcomes - drop-outs	Low risk	36 Patients entered the trial but four were lost to follow-up for various reasons, leaving 32. Of these, three defaulted in the final week, but their results up to that time have been included
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Unclear risk	Not stated.
Selective reporting (reporting bias)	High risk	No published protocol; back-pain specific functional status not reported
Group similarity at baseline	Low risk	Baseline gender distribution, age range, duration of back pain, patient's height, weight, site of pain, character of the pain and the effects of movement, coughing, and sneezing of the pain were compared (most of these data were not presented). According to the authors: The distribution of all these parameters were similar in the two TX groups and in no instance did the groups differ from one another significantly
Influence of co-interventions	Low risk	Standardized co-intervention: codeine phosphate 2 caps of 16 mg when necessary. Pain scores correlated significantly with the number of codeine capsules consumed each week; therefore, number of capsules consumed per group. over the 3-wk. period were not analysed separately
Compliance with interventions	Unclear risk	Not stated.
Timing of outcome assessments	Low risk	

Ferreira 2007

Methods	RCT; allocation adequately conducted
Participants	240 patients randomly allocated to 3 treatment groups; setting: physical therapy departments at 3 teaching hospitals in Sydney, Australia; recruitment period - May 2002 to November 2003 Age: grp.1- 54.8 (15.3); grp.2 - 51.9 (15.3); grp.3 - 54.0 (14.4) Gender (% F): grp.1- 70.0%; grp.2 - 66.3%; grp.3 - 70.0% Inclusion criteria: non-specific LBP $\geq$ 3 months, 18 to 80 years of age. Patients with osteoarthritis or disc lesions (prolapse, protrusion, or herniation without neurological compromise) were also eligible Duration of LBP: majority of patients across all grps. had > 3 yrs. of LBP Exclusion criteria: neurological signs, specific spinal pathology (e.g. malignancy, or inflammatory joint or bone disease) or previous back surgery
Interventions	1) General exercise (N = 80). Aim was to improve physical functioning and confidence in using the spine, and to teach participants to cope with their back problems; exercises were performed under the supervision of a physical therapist in classes of up to 8 people with each class lasting approximately 1 hour. The intensity of the exercises was progressed over the 12 treatments; the class was modelled on the "Back to fitness" program described by Klabber-Moffet and Frost 2) Motor control exercise (N = 80). Aim was to improve function of specific trunk muscles thought to control movement of the spine; Each participant was trained by a physical therapist to recruit the deep muscles of the spine and reduce activity of other muscles. Initially participants were taught how to contract the transversus abdominis and multifidus muscles in isolation from the more superficial trunk muscles, but in conjunction with the pelvic floor muscles. Ultrasonography was used to provide feedback about muscle recruitment Both exercise groups also received cognitive-behavioural therapy. This was designed to encourage skill acquisition by modelling, the use of pacing, setting progressive goals, self monitoring of progress, and positive reinforcement of progress. Self-reliance was fostered by encouraging participants to engage in problem-solving to deal with difficulties rather than seeking reassurance and advice, by encouraging relevant activity goals, and by encouraging self-reinforcement 3) SMT (N = 80). Maitland joint mobilization or manipulation techniques applied by physical therapists; dose and techniques were at the discretion of the therapist; participants were not given exercises or a home exercise program and were advised to avoid pain-aggravating activities As noted by the authors: Although all physical therapists were qualified to apply all three interventions, additional training was provided on administration of general exercise, motor control exercise and spinal manipulative therapy All participants were requested to attend up to 12 treatment sessions over an 8 week period, except for the SMT group, who were allowed to discontinue if their were recovered
Outcomes	Primary outcome measures (as determined by the authors): Perceived recovery: Global perceived effect (GPE, presented as a continuous variable, measured on a 11-point scale) ; Patient-specific functional scale (PSFS); Secondary outcome measures: Pain (11-point VAS); Back-pain specific functional status: Roland-Morris; adverse events - not reported. Follow-up: 8 weeks, 6 and 12 months

Notes	Authors results and conclusions: The motor control exercise group had slightly better outcomes than the general exercise group at 8 weeks as did the SMT group. All groups had similar outcomes at 6 & 12 months. Motor control exercise and SMT produce slightly better short-term function and perceptions of effect than general exercise, but not better medium or long-term effects Funded by Arthritis Foundation of New South Wales, the Motor Accidents Authority of New South Wales, and the University of Sydney Principal author is a physiotherapist and all authors cited work in physiotherapy departments

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomization was by a random sequence of randomly permuted blocks of sizes 6, 9 and 15; consecutively numbered, sealed, opaque envelopes used
Allocation concealment (selection bias)	Low risk	The randomisation schedule was known only to one investigator who was not involved in recruiting participants, and it was concealed from patients and the other investigators using consecutively numbered, sealed, opaque envelopes
Blinding (performance bias and detection bias) All outcomes - patients	High risk	There is no mention of attempts to blind the patients to other interventions or their perceptions of potential effectiveness of the different interventions
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". Below includes the authors attempt at blinding the "outcomes assessor" Participants reported their outcomes to a trial physical therapist who was blinded to allocation. The statistician was given grouped data, but data were coded so that the statistician was blinded to which group
Incomplete outcome data (attrition bias) All outcomes - drop-outs	Low risk	At 8 weeks follow-up (% retained): group 1 - 93% (74/80); grp.2 - 91% (73/80); grp.3 - 96% (77/80) At 6 months: grp.1 - 89% (71/80); grp. 2 -

Ferreira 2007 (*Continued*)

		85% (68/80); grp.3 - 90% (72/80) At 12 months: grp.1 - 91% (73/80); grp.2 - 81% (65/80); grp.3 - 91% (73/80)
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Low risk	Analysis was by intention-to-treat in the sense that data were analysed for all randomised subjects for whom follow-up data were available. No attempt was made to impute values for missing data. Consequently cases with missing data at a particular follow-up (8 weeks, 6 or 12 months) were dropped from analyses at that follow-up
Selective reporting (reporting bias)	Low risk	Study protocol available (ACTRN012605000053628; see http://www.anzctr.org.au/trial_view.aspx?ID=83). All 3 primary outcomes were reported; however, recovery was presented as a continuous measure
Group similarity at baseline	Low risk	
Influence of co-interventions	Unclear risk	Participants in all groups were asked not to seek other treatments and where possible not to change current medications for the 8 week trial period; however, they were permitted to seek alternate care after the 8 week intervention period
Compliance with interventions	Low risk	There was a high degree of adherence to all three interventions. Of the possible 12 sessions, participants in the general exercise group attended 9.1 ± 3.9 (mean ± SD) sessions, participants in the motor control exercise group attended 9.2 ± 3.4 sessions, and participants in the spinal manipulative therapy group attended 9.8 ± 2.7 sessions
Timing of outcome assessments	Low risk	

Ghroubi 2007

Methods	RCT; allocation procedure unclear. 1:1 Randomization scheme.
Participants	64 participants randomly allocated to 2 treatment groups; setting: university hospital (physical medicine rehabilitation department); study conducted in Tunesia. No statement on period of recruitment Age (mean (SD)) overall: 38.2 (9.4) years

Ghroubi 2007 (*Continued*)

	Gender (%F): overall - 80%F; 13M Inclusion criteria: 18-55 years of age; first episode of chronic low-back pain; presenting at time of palpatory examination with contracture of paravertebral muscles and/or minor intervertebral derangement. Nature of radiating pain: without sciatica Duration LBP: range: 16 to 19 months. Exclusion criteria: if patient had tumour or inflammatory pathology; trauma in the 6 weeks preceding the study; fracture, osteoporosis, lumbosacral radiculopathy or pain radiation into the buttocks, spondylolisthesis, scoliosis, previous spinal surgery, pregnancy, severe psychiatric illness
Interventions	1) Spinal manipulation (N = 32): according to the text: the type of manipulation chosen was dictated by the nature of the initial clinical presentation. Comment: no further description of the training, experience of the manipulator(s?) (physical or manual therapist?) is given nor the specific technique used. 2) Sham spinal manipulation (N = 32): consisting of putting tension on the spine without receiving a manipulative impulse or thrust Both groups underwent 4 treatments (in total), weekly for 4 weeks by the same manipulator. Comment: Probably just one manipulator and delivered the treatment for both groups (but this is unclear)
Outcomes	Pain: VAS, 10-cm; Back-pain specific functional status: Oswestry; Patient satisfaction (0 to 100-point scale, ranging from not satisfied to completely satisfied); Schober's test; palpatory tenderness with skin rolling; palpatory tenderness of the spinal processes; contracture of the paravertebral muscles; recovery - not reported; adverse events - not reported; comment: Outcome measures not defined as primary or secondary by the authors) Follow-up: 1 and 2 months
Notes	Authors results and conclusions: Patients receiving true SMT showed significant improvement in pain relief and functional status, which persisted into the second month. Our study confirms the efficiency of short-term vertebral manipulation for treating chronic LBP Funded by: not stated. Principal author is medical doctor (physical medicine and functional rehabilitation); one co-authors is a rheumatologist, and further is unclear Study published in French.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Patients randomised by drawing lots. Comment: No further text was provided as to the actual sequence generation or randomisation procedure nor who was involved and whether this was performed by an independent researcher
Allocation concealment (selection bias)	Unclear risk	Not stated.

Blinding (performance bias and detection bias) All outcomes - patients	Unclear risk	According to the text, patients were blinded to treatment, but it is unclear if this was successfully performed as this was not evaluated at the end of the study
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	Unclear risk	Patient unclear blinding. Outcomes assessed by a blinded outcomes assessor within the clinic for both follow-up measurements; however, no mention of the success of the blinding by the patients
Incomplete outcome data (attrition bias) All outcomes - drop-outs	Low risk	As determined from Table 5 (reporting of the outcome measures). No drop-outs in either grp. at the last follow-up interval (2 months)
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Unclear risk	Not reported.
Selective reporting (reporting bias)	High risk	No published protocol; recovery not reported.
Group similarity at baseline	Low risk	Baseline characteristics presented for age, gender, Schober's test, Oswestry, duration LBP, level of pain, profession (no, sedentary or heavy labor), activity levels (sport), currently receiving other treatments (pain medication and/or anti-inflammatory - 84% for the SMT grp. and 75% for the sham SMT group.), presence/absence of derangement or contracture of the paravertebral muscles
Influence of co-interventions	Unclear risk	No mention of co-intervention use for either group.
Compliance with interventions	Low risk	No drop-outs throughout the course of the study; thus, presumably all patients would have attended the prescribed number of visits/treatments
Timing of outcome assessments	Low risk	At 1 and 2 months post-baseline.

Gibson 1985

Methods	RCT; method of allocation assignment unclear.
Participants	109 patients randomly allocated to 3 treatment groups; setting: hospital outpatient department in London, UK; no statement on period of recruitment Age (mean(SD)): grp.1 - 34 (14); grp.2 - 35 (16); grp.3 - 40 (16) Gender (% F): grp.1 -51%; grp.2 - 47%; grp.3 - 32% Inclusion criteria: LBP greater than 2 months, but less than 12 months Duration of the present LBP: Range: 16 to 18 wks. Radiation pattern of pain: unclear Exclusion criteria: h/o numbness, paraesthesias, pain worsened by coughing, spondylolysis or -listhesis, treatment elsewhere (excluding use of analgesics), demonstrable neurological deficit, or specific spinal disease (inflammatory, metabolic, or neoplastic)
Interventions	1) Osteopathic manipulation and mobilization (N = 41); 2) Short-wave diathermy (SWD) (N = 34); 3) Placebo (detuned diathermy) (N = 34) Diathermy: Both active and detuned diathermy were given by one physiotherapist and consisted of in total 12 treatments per intervention (3 per week for 4 weeks). The detuned SWD machine was switched on so that the electrical noise and display light gave the impression that the instrument was in use. The physiotherapist was equally attentive to patients receiving real and simulated SWD The osteopath was a qualified, non-medical practitioner whose attachment to Guy's Hospital department of rheumatology for the study was without precedent. He treated patients once weekly for 4 weeks (thus 4 treatments in total). The osteopathic regimen included examination, soft-tissue manipulation, passive articulation of stiff spinal segments, and manipulation of the vertebral facet or sacroiliac joints using minimal rotation
Outcomes	Pain (100-mm VAS - daytime and nocturnal scores); Back-pain specific functional status - not reported; recovery (% patients pain free); analgesic consumption (% patients); spinal tenderness (4-point scale, dichotomized to % patients with moderate or severe tenderness *versus* none or mild tenderness); lumbar spine flexion (using the method of Macrae and Wright); return-to-work or activities of daily living (% patients unable to work or carry out household tasks); adverse events - not reported; comment: Outcomes not defined as primary or secondary by the authors Follow-up: 2, 4, 12 wks.
Notes	Funded by Arthritis and Rheumatism Council; author works in the Dept. of Rheumatology, Guy's Hospital, London Authors results and conclusions: More than half of the subjects in each of the 3 grps. benefited immediately from therapy. Significant improvements were observed in the 3 grps. at the end of 2 wks. tx. and these were still apparent at 12 wks. Benefits obtained from osteopathy and SWD may have been achieved through a placebo effect

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	The patients were randomly allocated to 3 tx. grps., which were stratified for age and duration of symptoms

Gibson 1985 (*Continued*)

Allocation concealment (selection bias)	Unclear risk	Note: no other text was provided on sequence generation or allocation
Blinding (performance bias and detection bias) All outcomes - patients	High risk	There is no mention of attempts to blind the patients to other interventions or their perceptions of potential effectiveness of the different interventions
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". Below includes the authors attempt at blinding the "outcomes assessor" Serial assessments of each patient were made by one doctor who was unaware of the treatment allocations. During the study period 3 different doctors had this role. Patient assessments were carried out immediately before and then 2 and 4 weeks after the start of treatment, and a final assessment was conducted at 12 weeks (presumably in the clinic) Patients who did not complete their treatment or did not attend for assessment were sent a postal questionnaire which asked the reasons for non-attendance and enquired about the response to treatment
Incomplete outcome data (attrition bias) All outcomes - drop-outs	Low risk	At 2 wks (% retained): grp.1 - 95% (39/41) ; grp.2 - 94% (32/34); grp.3 - 100% (34/34) At 4 wks: grp.1 - 95% (39/41); grp.2 - 94% (32/34); grp.3 - 97% (33/34) At 12 wks: grp.1 - 93% (38/41); grp.2 - 79% (27/34); grp.3 - 94% (34/34)
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Unclear risk	Not explicitly stated. Participants did not return for assessment at various intervals because they were pain-free. It is unclear from the analysis if these data were included in subsequent measurements, although it might appear that these values were "carried forward"

Gibson 1985 (*Continued*)

Selective reporting (reporting bias)	High risk	No published protocol was available; data for back specific functional status was not measured/reported
Group similarity at baseline	High risk	Number of patients assigned to the placebo grp. who needed analgesics, who were unable to work or had restricted ADL's, who had moderate or severe spinal tenderness, or less spinal flexion was (much) higher *versus* osteopathy or SWD grp. On the other hand, median pain level and duration of the pain was similar across the grps
Influence of co-interventions	Unclear risk	Not stated.
Compliance with interventions	Low risk	Not explicitly stated, but based upon % of the study grp. retained, it would appear that compliance was adequate
Timing of outcome assessments	Low risk	

Goldby 2006

Methods	RCT; unclear allocation procedure.
Participants	323 patients randomly allocated to 3 treatment groups; setting: 2 physical therapy departments in hospital in the UK; recruitment conducted March 1998 to November 1999 Age: grp.1 - 43.4 (± 10.7); grp.2 - 41.0 (± 11.7); grp.3 - 41.5 (± 13.0) Gender % F: grp.1 - 68%; grp.2 - 69.9%; grp.3 - 67.5% Inclusion criteria: LBP > 12 weeks, age 18 to 65 years, understanding of English Duration of the LBP (mean (SD) in yrs.): overall 11.7 (9.9). Radiation pattern of pain: with or without leg pain (beyond the knee) Exclusion criteria: non-mechanical LBP; specific spinal condition (stenosis, spondylolisthesis grade III or IV, or recent fracture); significant or worsening neurological deficit; inflammatory joint disease; lower limb pathology; present or past h/o metastatic disease; medically unsuitable for exercise class; chronic pain syndrome or h/o $\geq$ 2 previous low-back surgeries; h/o anxiety neurosis; pregnancy
Interventions	1) Spinal stabilization rehabilitation program (N = 84): aim was to rehabilitate the neural control and active subsystems of the lumbar spine's stabilizing system; ten one-hour classes were given; max. 12 patients per class 2) Manual therapy (N = 89): any form of exercise or manual therapy procedure within the remit of musculoskeletal physiotherapy; however, the therapists were not allowed to prescribe exercises for the abdominal muscles or pelvic floor, nor were they allowed to use electrophysical methods; patients were discharged at discretion of the therapist or to a max.10 sessions 3) Education (control) "minimal intervention" (N = 40): educational booklet "Back in Action"

	All groups received Back School, which consisted of 1 group specific 3-hour question and answer session. The class covered anatomy, biomechanics and lifting, pathologies, and advice on education, exercise, and general fitness
Outcomes	Pain: 100-point NRS (back pain, leg pain); Back-pain specific functional status: Oswestry, Low-Back Outcome score; Quality of life: Nottingham Health Profile; Impairment: lumbar flexion (mm); timed walking test; recovery - not reported; adverse events - not reported. Note: Outcomes were not defined as primary or secondary by the authors. In addition, medication use is cited as an outcome in the tables (no. of patients, days per week), but is not cited in the text Follow-up at 3, 6, 12, and 24 months
Notes	Funded by "professional organizations". Authors results and conclusions: Spinal stabilization is more effective than manually applied therapy or an education booklet in treating chronic LBP. Both manual therapy and spinal stabilization program were significantly effective in pain reduction as compared to an active control Principal author is not a physiotherapist, but works in dept. for physiotherapy Unclear what techniques were actually used in the manual therapy intervention. i.e. whether this consisted of mobilization, manipulative or muscle energy techniques

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Numbers were generated using a computer package, Clinstat, and blocks of random numbers were created
Allocation concealment (selection bias)	Unclear risk	After signing informed consent, the research assistant collected the data related to the dependent variables and informed the researcher of the details required to allocate randomly the subject. At all times, the research assistant remained blind to the patients' group allocation. Patients were randomly allocated to one of the groups using a stratification procedure. Unclear what safeguards were taken to blind randomisation sequence
Blinding (performance bias and detection bias) All outcomes - patients	High risk	There is no mention of attempts to blind the patients to other interventions or their perceptions of potential effectiveness of the different interventions
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups

Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". Below includes the authors attempt at blinding the "outcomes assessor" The research assistant collected the dependent variables and questions covering activity, socioeconomic conditions and medication. At all times, the research assistant remained blind to the patients' group allocation. Outcomes consisted of self-report measures
Incomplete outcome data (attrition bias) All outcomes - drop-outs	Low risk	Follow-up at 3 months (% retained): grp.1 - 93% (78/84); grp.2 - 96% (85/89); grp.3 - 93% (37/40) At 6 months: grp.1 - 87% (73/84); grp.2 - 85% (76/89); grp.3 - 63% (25/40) At 12 months: grp.1 - 85% (71/84); grp.2 - 83% (74/89); grp.3 - 70% (28/40) At 24 months: grp.1 - 42% (35/84); grp.2 - 42% (37/89); grp.3 - 48% (19/40) Note: percentage drop-out for the 2-year follow-up varies from Table 1 (those in the table are presumably incorrect because the number of subjects is incorrect)
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	High risk	Not stated in the methods; however, the following was stated: Of the 346 subjects booked for initial assessment, 44 (12% of the entry population) were excluded between signing informed consent and commencing treatment. Of the 302 subjects remaining, a number (see later) failed to attend any treatment sessions. Furthermore, some subjects withdrew consent during treatment, and the researcher withdrew (from the data analysis stage) those subjects from the 2 active groups (A and B) who failed to attend more than once
Selective reporting (reporting bias)	High risk	Recovery not reported. No published protocol. Medication use is cited as an outcome in the tables (no. of patients, days per week), but is not cited in the text as an outcome
Group similarity at baseline	Low risk	
Influence of co-interventions	Unclear risk	Not stated.
Compliance with interventions	High risk	There were 17 subjects who failed to attend any treatment sessions, and 18 were withdrawn for failing to attend more than once (Table1). Three subjects in the manual therapy group were pre-

		scribed (in error) individual spinal stability exercises. They were also withdrawn from the data analysis. There was a higher dropout rate for the education group
Timing of outcome assessments	Low risk	

Gudavalli 2006

Methods	RCT; adequate allocation procedure.
Participants	235 patients randomly allocated to 2 treatment groups; setting: two chiropractic and two orthopaedic clinics in Chicago, USA; recruited via radio and newspaper advertisements, press releases, cable television advertisements, local posters, and local electronic sign advertisements; period of recruitment not presented Age (mean(SD) in years): grp.1 - 42.2 (11.4); grp.2 - 40.9 (12.8) Gender (% F): grp.1 - 34.2%; grp.2 - 41.1% Inclusion criteria: age > 18 years, primary complaint of LBP (from L1 to SI joint), duration longer than 3 months, palpatory tenderness over one or more lumbar zygapophyseal joints; willing to forego narcotic use during the treatment phase of the study as well as NSAID use and/or muscle relaxants for 24 h. prior to baseline or at time of outcome assessment Duration of LBP: unclear. Radiation pattern of pain: with or without radiculopathy Excluded if: evidence of central nervous system (CNS) disease; contraindications to manual therapy (e.g. severe osteoporosis, lumbar fracture, systemic disease, failed fusion surgery, inability to undergo physiotherapy or flexion-distraction for any other reason); psychiatric illness; current or known substance abuse; not fluent and/or illiterate in the English language; morbidly obese; pregnant; currently receiving care elsewhere for LBP; treated by chiropractor or PT in the past 6 months; not willing to forego care elsewhere during the treatment phase; limitation or inability to carry out physical activity without discomfort
Interventions	1) Flexion-Distraction (traction and mobilization) (N = 123): performed on specially constructed table with moveable headpiece, stationary thoraco-lumbar piece, and a moveable lower extremity piece; first component consisted of traction using the flexion ROM directed at a specific joint level; the second component was a series of mobilization procedures; Patients also received ultrasound and cryotherapy; the intervention was administered by chiropractors with post-graduate certification in this technique 2) Exercise therapy (administered by licensed physical therapists and consisted of flexion or extension exercise, weight training, flexibility exercises, and cardiovascular training) (N = 112). The aim of the program was to strengthen the muscles surrounding the spine and increase flexibility; methods used for the stabilizing exercises were consistent with those of O'Sullivan Study participants in both treatment grps. were seen 2 to 4 times per week at the discretion of the treatment provider, for a total of 4 weeks
Outcomes	Primary outcomes (as defined by the authors): Pain (100-mm VAS); Back-pain specific functional status (Roland-Morris); Generic general health (SF-36; 8 sub-scales presented individually as well as overall score). Secondary outcomes: health care utilization, low-

	back biomechanics, patient satisfaction (3 questions: "Overall, how much were you helped?"; "In the future, would you return to this type of care?"; "Would you recommend this type of care to family or friends?"; adverse events - no adverse events or side-effects were reported by subjects from either intervention. Results presented separately with and without radiculopathy Follow-up: 4 weeks, 3, 6, 12 months
Notes	Authors results and conclusions: Flexion-distraction provided more pain relief than active exercise; however, these results varied based upon stratification of patients with and without radiculopathy and with and without recurrent symptoms Funded by Health Resources and Services Administration, National Chiropractic Mutual Insurance Company Principal author works as a researcher at the chiropractic college where the study was conducted; 3 of the 7 authors are chiropractors, including the principal author Significantly more subjects dropped out of the study from the exercise grp.; unclear how radiculopathy was defined; subjects were not allowed pain medication in the first 4 weeks, but no restriction after that Definition of radiculopathy (personal communication with the primary author), although this was not defined in any of their reports: The leg pain category (radiculopathy) is defined as a patient presentation with symptoms in the lumbar spine and/or leg and foot region distal to the knee. These patients exhibit hard clinical evidence of neurological involvement such as dermatomal pain or sensory and/or motor deficit usually involving L4, L5, and S1 nerve roots." Nerve root involvement is verified by (1) provocation of symptoms distal to the knee through Valsalva maneuver and the SLR nerve root tension test (2) reduction in deep tendon reflexes related to the nerve root and (3) specific muscle weakness related to the nerve root In Table 5 of Cambron JA et al J Alternative Compl. Medicine 2006 - Std. errors are presented instead of the SD (incorrectly stated in the heading of the table) The authors were also contacted regarding inconsistencies in the follow-up data for the 2 different reports (Gudavalli et al. European Spine J 2006; Cambron et al. J Alt Comp Medicine 2006). The data reported in Gudavalli (Table 8) is not consistent with the data reported in Cambron (Table 5). Here, the change scores are presented for the 2 interventions at the various follow-up periods. This cannot be explained by the number of subjects analysed because they were the same in both reports. No reply was received regarding further explanation

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random number tables were used.
Allocation concealment (selection bias)	Low risk	Sequentially numbered sealed manila envelopes held each successive randomised treatment group allocation. At the time of randomisation the research assistant opened the next numbered envelope and the subject was allocated accordingly. The allocation sequence was generated by

		the clinical co-coordinator. Neither the clinician who first saw the patient nor the patient who agreed to participate in the study was involved in the allocation to intervention group
Blinding (performance bias and detection bias) All outcomes - patients	High risk	There is no mention of attempts to blind the patients to other interventions or their perceptions of potential effectiveness of the different interventions
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". Below includes the authors attempt at blinding the "outcomes assessor" The primary outcome measures were self-administered questionnaires distributed by the research assistants. Study participants were given blank questionnaires at each assessment point and placed completed forms in an envelope. Subjects then sealed the envelope and returned it to the research assistant. Research assistants remained blinded to outcome data for the entire study period and were counselled by the research investigators and clinical coordinator, regarding the importance of blinding. They were trained in administration of informed consent and outcome data retrieval using simulated patients. Meetings between the research co-coordinator, principal investigator and providers responsible for treatment were held on a regular basis throughout the study to facilitate quality control. No incidents of unblinding were reported
Incomplete outcome data (attrition bias) All outcomes - drop-outs	High risk	At 1 month (% retained): grp.1 - 89% (109/123); grp.2 - 78% (87/112) At 3 months: grp.1 - 71% (87/123); grp.2 - 68% (76/112) At 6 months: grp.1 - 73% (90/123); grp.2 - 70% (78/112) At 12 months: grp.1 - 78% (96/123); grp.2 - 70% (78/112) A total of 197 subjects (83.4%) completed the intervention phase. Of the 38 dropouts, 13 were from FD and 25 from ATEP (exercise grp). Primary reasons for study withdrawal were dimin-

Gudavalli 2006 (*Continued*)

		ished interest and scheduling difficulties. Table 3 provides these data according to group membership. A difference in proportions test indicated that significantly more subjects dropped out of the study from ATEP. The majority listed "no longer interested in participation" as their reason for withdrawal
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	High risk	ITT analysis was conducted only at the first follow-up measurement (at 4 weeks); subsequent analyses were "per-protocol"
Selective reporting (reporting bias)	High risk	Recovery not reported. No published protocol was available.
Group similarity at baseline	Low risk	
Influence of co-interventions	Unclear risk	Not stated.
Compliance with interventions	Unclear risk	Not stated what was considered acceptable and how many sessions were attended in the different groups
Timing of outcome assessments	Low risk	

Hemmila 2002

Methods	RCT; adequate allocation.
Participants	132 patients randomly allocated to 3 treatment groups; setting: primary care centre; recruited by colleagues in a local health center or via articles and announcements in newspapers; conducted in Finland; period of recruitment February to June 1994 Age: overall 41.9 years (range 17 to 64) Gender: 43% F (49/114) Inclusion criteria: subacute and chronic back pain (> 7 weeks) with and without radiation below knee; pain between the shoulders and buttocks Duration of LBP: mean - 7.5 years; range 60 days to 40 years Exclusion criteria: retirement, pregnancy, malignancy, rheumatic diseases, severe osteoarthritis, cauda equina syndrome, back operation, or vertebral fracture in the past 6 months or any condition that would prevent or contraindicate any of the therapies. None of the study treatments were allowed during the previous month. Patients also had to have a minimum pain level of 25mm on a 100-mm visual analogue scale (VAS)
Interventions	1) Bone-setting (BS) (N = 45): delivered by 4 folk-healers aged 40 to 70 years with a practical experience of up to 30 years, but with no formal medical education. The bone-setters were free to choose the methods from their repertoires. The method they most commonly applied was gentle mobilization of the spine. The patient sits on a stool with the therapist behind him. The therapist first uses his fingers to find out if the spinous processes are in line or "dislocated" up or down or on either side. If a vertebra is found

	to be "out of alignment," the patient is asked to bend forward and slowly straighten up while the therapist holds his thumbs against the transverse processes of the next lower vertebra, thus presumably mobilizing the upper facet joints. Another common method is simply to rub the "misaligned" spinous processes gently from all sides to "negotiate" them into a "correct position." Massage was applied occasionally. No direct and forceful, "chiropractic" manipulations were used; mean no. treatments = 8.1 (2.7) The 2002 report states that this therapy is consistent with chiropractic or osteopathy 2) Physiotherapy (N = 34): combination of manual, thermal, and electrotherapy. The therapist was free to choose a suitable method within these categories and to use the facilities at his disposal: hot/cold packs, infrared heat, ultrasound, shortwave diathermy, and transcutaneous electric nerve stimulation. In addition to massage, he also employed specific mobilizations and manual traction according to the GP's prescription, but no manipulations with impulse. Individual auto-stretching exercises were added if indicated; mean no. treatments = 9.9 (0.7) 3) Home exercises with individual instruction by PT (N = 35); patients were taught a constant program: to bend their low back rhythmically from side to side and back and forth as well as to rotate from side to side, ten times in each direction every 1.5 minutes, whenever sitting, standing, or lying still (e.g., watching TV, driving a car) or at least before getting up in the morning and after lying down in the evening. The program also included 10 sit-up, 10 arch-up, and 10 trunk rotation exercises twice a day; mean no. treatments = 4.5 (2.2) A maximum 10 1-hour sessions of each therapy was offered; 6-week treatment program
Outcomes	Pain (100-mm VAS); Back-pain specific functional status (Oswestry); spinal mobility (Schober); side bending (degrees); extension (degrees); straight leg raising (degrees); pressure pain threshold level (measured by a dolorimeter); pain provocation score (calculated from the reactions to 13 tests of spinal and lower limb mobility, piriformis provocation tests, and sacroiliac provocation tests); use of health resources (i.e. visit to health centers, sick-leave days, percentage of patients sick-listed - from the 2002 publication); recovery - not reported; adverse events - not reported. (Comments: Outcomes not defined as primary or secondary by the authors.) Follow-up: 6 weeks, 3 and 6 months
Notes	Authors results and conclusions: Oswestry disability scores improved most in the bone-setting group. Traditional bone-setting seemed more effective than exercise or physiotherapy for back pain and disability, even one after therapy Funded by Finnish Slot Machine Association and conducted in the facilities at the Folk Medicine Centre of Kaustinen The authors recognize that a "considerable number of patients" from the exercise and physiotherapy group switch over to bone-setting after the 6-week treatment period 2002 publication is the long-term analysis with this data set. In the 1997 report, it explicitly states that no direct or forceful "chiropractic" manipulations were used, while the 2002 report states that bone setting is consistent with chiropractic or osteopathy. The physiotherapy grp. was allowed to perform specific mobilizations, but not manipulations with impulse (cf. bone-setting grp.)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Random sequence generation (selection bias)	Low risk	drawing sealed lots
Allocation concealment (selection bias)	Low risk	A study nurse first registered and interviewed the patients, obtained a written consent, and finally randomised the patients by drawing sealed lots after a general practitioner had completed the baseline clinical examinations and measurements. The nurse also delivered the questionnaires and booked the follow-up therapy sessions, keeping the general practitioner strictly blind to the randomised therapies Note: this detailed information was found in the follow-up study; information on the randomisation procedure were lacking in the original 1997 study
Blinding (performance bias and detection bias) All outcomes - patients	High risk	There is no mention of attempts to blind the patients to other interventions or their perceptions of potential effectiveness of the different interventions
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". Below includes the authors attempt at blinding the "outcomes assessor" A single general practitioner, blinded for the therapies, carried out all the physical examinations: before the randomisation and 6 weeks and 6 months later, following the guidelines recommended for occupational health controls
Incomplete outcome data (attrition bias) All outcomes - drop-outs	Low risk	At 6 weeks (% retained): grp.1 - 98% (44/45); grp.2 - 100% (34/34); grp.3 - 100% (35/35) At 6 months: grp.1 - 98% (44/45); grp.2 - 100% (34/34); grp.3 - 100% (35/35) At 1 year: grp.1 - 98% (44/45); grp.2 - 94% (32/34); grp. 3 - 91% (32/35)
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Unclear risk	ITT analysis conducted, but unclear why data on the acute low-back pain subjects (N=18) was not included in the analysis and whether this formed an *a priori* strategy.
Selective reporting (reporting bias)	High risk	No published protocol was available; disability and recovery were not reported
Group similarity at baseline	Low risk	

Hemmila 2002 (*Continued*)

Influence of co-interventions	High risk	Patients were advised in the beginning not to take any therapy other than that to which they were randomised. One patient (3%) from the physiotherapy group had consulted a physiotherapist and 8 (24%) a bonesetter. During follow-up one patient from the exercise group was operated on for a herniated disc and one from the bone-setting group was referred to a rehabilitation center From the 1997 publication: 41% of the physiotherapy, 58% of the bone-setting, and 44% of the exercise patients took some form of therapy during the follow-up period (comment: unclear what this therapy consisted of and whether it was therapy other than to which the patients were randomised); however, the authors state in the discussion that "... the exercise and the physiotherapy patients tended to switch over to bone-setting after the 6-week treatment period." 76% of the physiotherapy patients (N = 26/34), 89% of the bone-setting patients (N = 40/45), and 57% of the exercise patients (N = 20/35) did not seek other therapy to which they were randomised
Compliance with interventions	Low risk	Half of the exercise patients reported having done at least three quarters of the required home exercises during the 6-week treatment period. After 3 months 32 exercise patients (80%), and after 6 months 19 (54%), still reported having continued the exercises, while 4 (11%) had physiotherapy and 8 (23%) bone-setting therapy. Twelve bone-setting patients (27%) had continued on bone-setting and 3 (7%) had received physiotherapy
Timing of outcome assessments	Low risk	

Hondras 2009

Methods	RCT; adequate allocation procedure
Participants	240 participants randomly allocated to 3 treatment groups; setting: chiropractic research clinic; conducted in Iowa, USA; participants recruited via newspaper, radio, television, community magazines, flyers, direct mail postcards, health fairs, community-based focus groups, and word of mouth were sources of advertising and promotion. Specialty community publications targeted older adults. Recruitment period: July 2004 - September 2006 Age (mean (SD)): overall: 63.1(6.7) Gender (% F): overall: 44% Inclusion criteria: at least 55 years old, non-specific low-back pain of at least 4 weeks duration, and met the following diagnostic classification: pain without radiation, radiation to extremity, proximally or radiation to extremity, distally according to the Quebec Task Force on Spinal Disorders. 85% of the population had LBP without radiation or

Hondras 2009 (*Continued*)

	LBP w/ radiation to proximal extremity Duration LBP episode (mean (range)): 9.6 to 15.1 years. Exclusion criteria: LBP associated with frank radiculopathy or neurological signs such as altered lower extremity reflex, dermatomal sensory deficit, progressive unilateral muscle weakness or motor loss, symptoms of cauda equina compression, or computed tomography or magnetic resonance imaging evidence of anatomical pathology (e.g., abnormal disc, lateral or central stenosis); comorbid conditions or general poor health that could significantly complicate the prognosis of LBP, including pregnancy, bleeding disorders, and clear evidence of narcotic or other drug abuse; major clinical depression defined as scores greater than 29 on the Beck Depression Inventory-Second Edition; bone or joint pathology that contraindicated SMT of the lumbar spine and pelvis, including spinal fractures, tumours, infections, arthropathies, and significant osteoporosis; pacemaker because of safety issues; current or pending litigation related to this LBP episode; receiving disability for any health-related condition; received SMT for any reason within the past month; unwilling to postpone the use of manual therapies for LBP except those provided during the study; unable to comprehend English
Interventions	1) High-velocity low-amplitude SMT (N = 96): side-lying diversified lumbar spine "adjustment" or maneuver. Participants were positioned in a lateral recumbent or side-lying position with the superior or free hip and knee flexed and adducted across the midline. The intent of the SMT was to isolate one or more vertebral segments. The impulse load was delivered by a quick, short, controlled movement of the shoulder, arm and hand combined with a slight body drop 2) Low-Velocity Variable Amplitude Spinal Mobilization (N = 95): flexion-distraction technique or Cox technique. Participants were positioned prone on a treatment table that was designed to allow free but controllable motion to the lower half of the participant's body. The distal section of the table also allowed the chiropractor to apply traction to the lumbar spine. During this maneuver, the intent was to stabilize a specific vertebra by applying anterior to posterior and cephalad pressure to the spinous process. Simultaneously, the chiropractor moved the lower mobile portion of the table through the ranges of motion normal to the human spine 3) Medical care (N = 49): All participants were scheduled to attend visits at week 3 and 6 to be evaluated by the medical provider and complete questionnaires. Additional visits were scheduled at the discretion of the medical provider. The goal of pain management was improvement in pain and optimisation of activities of daily living. The first option was paracetamol (acetaminophen), followed by NSAIDs and muscle relaxants Home Exercise Instruction: During week 3, the medical or chiropractic provider delivered 30 minutes of standardized instructions for a home exercise program to all participants enrolled in the trial. The exercise prescription guidelines were tailored to individual participant ability and instructed participants to begin an aerobic program as well as low-back stretching and strengthening exercises. Participants were given a handout with pictures of 7 low-back exercises, with the number of sets and repetitions tailored and delineated for each participant Participants receiving SMT or mobilisation were allowed to receive a maximum of 12 visits (not to exceed 3 times per week for the first 2 weeks, 2 times per week for the third and fourth weeks, and once per week during weeks 5 and 6) *versus* 3 visits of medical care. Four chiropractors delivered the chiropractic txs *versus* one medical physician who delivered this aspect of care.

Hondras 2009 (*Continued*)

Outcomes	Primary outcome (as determined by the authors): Back-pain specific functional status (Roland-Morris); Secondary outcomes: Pain (100-mm VAS); sub-scale of the FABQ; perceived recovery (11-point, verbal rating scale) - presented as a continuous outcome measure; SF-36 - physical function sub-scale. Adverse events were also reported but not listed as a primary or secondary outcome Adverse events: A total of 21 side-effects were reported by 20 participants - all resolved within 6 days and none required referral for outside care, although one participant from the medical group was referred for slurred speech. Side-effects were similar in the 2 SMT groups and consisted mostly of LBP soreness and stiffness Follow-up at 3, 6, 12, 24 weeks
Notes	Authors results and conclusions: Distinct forms of spinal manipulation did not lead to different outcomes in older LBP patients and both SMT procedures were associated with small yet clinically important changes in functional status by the end of treatment. Participants who received either form of SMT had improvements on average in functional status ranging from 1 to 2.2 points over those who received conservative medical care Funded by Bureau of Health Professions Health Resources and Services Administration, Rockville, MD, USA; and the work was conducted in a facility constructed with support from Research Facilities Improvement Program from the National Center for Research Resources, National Institutes of Health, Bethesda, MD, USA Primary author is a chiropractor and 3 of the 5 team members are chiropractors. All authors work at a chiropractic institution

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomly assigned by study co-ordinators through a Web interface to the adaptive computer generated randomisation to one of 3 interventions in a 2:2:1 treatment allocation ratio: HVLA-SMT, mobilization or medical care, respectively. All future assignments were concealed. Participant characteristics between groups were balanced by minimizing the baseline characteristics
Allocation concealment (selection bias)	Low risk	Comment: allocation was conducted through computer interface
Blinding (performance bias and detection bias) All outcomes - patients	High risk	There is no mention of attempts to blind the patients to other interventions or their perceptions of potential effectiveness of the different interventions
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups

Hondras 2009 (*Continued*)

Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". Below includes the authors attempt at blinding the "outcomes assessor" Assessments at baseline and weeks 3 and 6 (end of active care) were via self-administered questionnaires at the research clinic. Assessments at 12 and 24 weeks were administered via computer-assisted telephone interviews by trained interviewers who were masked to treatment assignment
Incomplete outcome data (attrition bias) All outcomes - drop-outs	High risk	Disconcordant drop-out in the medical intervention grp. At 3 wks. Follow-up (% retained): grp.1 - 98% (94/96); grp.2 - 92% (87/95); grp.3 - 65% (32/49) At 6 wks: grp.1 - 96% (92/96); grp.2 - 90% (85/95); grp.3 - 59% (29/49) At 12 wks: grp.1 - 97% (93/96); grp.2 - 90% (85/95); grp.3 - 76% (37/49) At 24 wks: grp.1 - 93% (89/96); grp.2 - 91% (86/95); grp.3 - 67% (33/49)
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Low risk	Multiple imputation procedure was used for missing data, subsequently the regression coefficients and P values between the results based on the original analyses that were performed on all available data were compared with that based on the multiple imputations. The results between the multiple imputation analyses were very similar to the original analyses for all outcomes; therefore, only the results from the original analyses are reported
Selective reporting (reporting bias)	Low risk	protocol published and available; all 3 primary outcomes reported
Group similarity at baseline	Low risk	
Influence of co-interventions	Unclear risk	Not stated.
Compliance with interventions	High risk	Not acceptable for the medical grp. Less than half attended all 3 prescribed visits, while 16% did not attend any visits; 20% withdrew from the study at some point during the 6-week active care period Eighty-three (86%) participants in the HVLA-SM group and 79 (83%) in the LVVA-SM group completed 12 intervention visits. An additional

Hondras 2009 (*Continued*)

		10 and 7 completed at least 10 visits in the 2 groups, respectively. Eight (16%) participants in the MCMC group did not attend any of their scheduled visits with the medical provider, 17 (35%) had one visit, 32 (65%) had 2 visits, 23 (47%) had 3 visits, and 4 (8%) had one extra visit. Of those who had at least one visit, 5 did not receive a prescription for their LBP, 27 were prescribed Celebrex, 5 Aleve, 3 Bextra, and one Naproxen
Timing of outcome assessments	Low risk	

Hsieh 2002

Methods	RCT; unclear allocation procedure
Participants	206 subjects randomly allocated to 4 treatment groups; setting: outpatient physical therapy clinic at the University of California Irvine Medical Center (UCIMC) and the Center for Research and Spinal Care at the Los Angeles College of Chiropractic (LACC), California, USA; participants recruited via public announcements and advertisements in major local newspapers and local radio stations as well as distribution of study brochures between May 8, 1996 and June 30, 1998 Age (mean (SD)): grp.1 - 47.9 (13.7); grp.2 - 49.0 (14.8); grp.3 - 47.4 (14.0); overall - 48.4 (13.7) Gender (% F): grp.1 - 40%; grp.2 - 33%; grp.3 - 33%; overall - 33% Inclusion criteria: 18 years of age or older, LBP duration of more than 3 weeks and less than 6 months for the current episode or a pain-free period of at least 2 months in the preceding 8 months for recurrent LBP Duration of the current episode (in Table 1 under the heading "Pain (wk)"): range: 10. 7 to 11.8 wks. (Note: this was confirmed by an e-mail to the principal investigators) Exclusion criteria: pregnancy; serious medical problems (e.g., advanced cancer, heart failure); definable neurologic abnormalities in the lower extremities (e.g., peripheral neuropathy, multiple sclerosis, hemiplegia, myelopathy); spine disorders with bony lesions (e.g., osteoporosis, fracture, unstable spondylolisthesis, multiple myeloma), with radiographs were taken as clinically indicated; significant mental disorders (e.g., psychosis, mania, major depression), as indicated by telephone inquiry and clinical interview; obesity (a Davenport body mass index exceeding 33 kg per meter of height1); leg pain with positive nerve root tension test results; litigation; automobile injuries; work injuries; inappropriate illness behavior (positive Wadell's sign); anticoagulant therapy; history of lumbar surgery; and use of the study treatments for the current episode
Interventions	1) Back school (N = 48): Each patient received the intervention once per week for a total of 3 weeks. During the first treatment visit, the patient watched three videos about spine anatomy, common causes of LBP, and body mechanics for daily activities.23 Subsequently, the patients received individual instructions and supervised practice of their home program by experienced licensed physical therapists and trained experienced licensed chiropractors. These programs included recommended sitting and standing neutral postures, body mechanics, and home exercises (lumbar flexion, extension, stretching,

Hsieh 2002 (*Continued*)

	and stabilization) 2) Myofascial therapy (N = 51): Each patient received therapy three times per week for 3 weeks. Trained clinicians (physical therapists and chiropractors) performed the myofascial therapy at each facility. The myofascial therapy program included intermittent Fluori-Methane sprays and 5 to 10 stretches after 3 to 5 seconds of each isometric contraction at 50 to 70% of their maximal effort, ischemic compressions using a massage finger, stripping massage along the orientation of the taut bands by the two thumbs for 3 to 5 strokes, and hot packs for 10 minutes at the completion of therapy. The involved lumbar paraspinal or gluteal muscles, as indicated by the examiner on the Assessment Recommendation form, were treated. Additional muscles also could be treated if clinically indicated 3) Joint manipulation (N = 49) : Each patient received therapy three times per week for 3 weeks. Experienced licensed chiropractors with a 5-year minimum of clinical experience delivered joint manipulation at both sites. The joint manipulations, consisting of high velocity and short-amplitude specific thrusting manipulations (the "Diversified" technique), were performed in the lumbar and/or sacroiliac regions (i.e., the tender locations indicated by the examiner on the Assessment recommendations form or other levels clinically deemed by chiropractor to need therapy). Side or sitting posture was allowed. Drop table techniques also were allowed. All treatments were given on Leander Model 900 EZ Tables. No flexion distraction or mobilization was allowed 4) Combination of treatments 2 & 3; N = 52
Outcomes	Primary outcomes (as defined by the authors): Pain (visual analogue scale); Back-pain specific functional status (Roland-Morris). Secondary outcomes: General health (36-Item Short-Form Health Survey); Minnesota Multiphasic Personality Inventory; confidence score and satisfaction; work or school lost days; adverse events; recovery - not reported. Results for the secondary outcome measures showed no apparent pattern and produced scattered statistically significant effects (according to the authors) - These data were not available in the publications adverse events - 23 patients reported adverse effects from the treatments: 7 in the combined group, 6 in the joint manipulation group, 4 in the myofascial therapy group, and 6 in the back school group. These adverse effects were mostly transient exacerbations of symptoms, except for one case of constant tinnitus in the myofascial therapy group. Two of the patients claimed that treatment (joint manipulation) had aggravated their conditions. Both received conservative care at no charge after 3 weeks of therapy and were released when their pain became stabilized Follow-up: 3 weeks and 6 months
Notes	Authors results and conclusions: All groups showed significant improvement in pain and functional status following 3 weeks of care, but did not show further improvement at 6 months. For subacute low-back pain, combined joint manipulation and myofascial therapy was as effective as joint manipulation or myofascial therapy alone. Additionally, back school was as effective as three manual treatments Funding: Human Resources and Service Administration, the Public Health Service, the Dept. of Health and Human Services, the Foundation for Chiropractic Education and Research, Leander Health Technologies (supplies chiropractic tables), and the Lloyd Table Company (also supplies chiropractic tables) Note: the duration of the current LBP is presented in Table 1 under "Pain (wk)" Follow-up to a similar study by these authors published in 1992 on subacute low-back

Hsieh 2002 (*Continued*)

	pain

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	After acceptance into the study, patients were randomised into one of four treatment groups using a computer program designed to balance allocation of patients according to age, gender, duration of LBP, and treatment preference for physical therapy or chiropractic. Randomization was performed separately at each site
Allocation concealment (selection bias)	Unclear risk	No other information was provided, e.g. whether the person who performed the allocation was an independent examiner; whether consecutively numbered, sealed opaque envelopes were used during allocation, etc
Blinding (performance bias and detection bias) All outcomes - patients	High risk	There is no mention of attempts to blind the patients to other interventions or their perceptions of potential effectiveness of the different interventions
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". Below includes the authors attempt at blinding the "outcomes assessor" Blinded independent examiners (physiatry residents at UCIMC and chiropractic residents at LACC) performed assessments (of the outcome measures) 1 to 2 days before the treatment started, 1 to 2 days after 3 weeks of care, and 6 months after the care. Five monthly telephone follow-up evaluations were conducted regarding work or school days lost, current pain level (0-10), use of health care services, and the Roland-Morris activity score. For this study, the primary efficacy variables were VAS pain and Roland-Morris activity scores
Incomplete outcome data (attrition bias) All outcomes - drop-outs	Low risk	92% (184/200) returned after 3 weeks of care and 89% (178/200) returned at 6 months At 3 wks (% retained): grp.1 - 88% (42/48); grp.2 - 96% (49/51); grp.3 - 94% (45/48); grp.4 -92% (48/52)

Hsieh 2002 (*Continued*)

		At 6 months: grp.1 - 88% (42/48); grp.2 - 92% (47/51); grp.3 - 83% (40/48); grp.4 -94% (49/52)
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Low risk	
Selective reporting (reporting bias)	Unclear risk	No published protocol available. Recovery not reported.
Group similarity at baseline	Low risk	
Influence of co-interventions	Low risk	During the 3-week trial period, only a minor proportion of the patients (10%) reported use of over-the-counter pain medications (e.g., ibuprofen, acetaminophen). Six patients reported eight visits to health care practitioners. Among these, two visits were related to LBP. Therefore, treatment contamination was insignificant After 3 weeks of therapy, 12 patients reported continuing care for LBP: 5 patients in the combined therapy group, 1 patient in the joint manipulation group, 3 patients in the myofascial therapy group, and 3 patients in the back school group. Altogether, 33 visits were reported: 16 visits in the combined therapy group, 1 visit in the joint manipulation group, 13 visits in the myofascial therapy group, and 3 visits in the back school group. During the study, 18 health care practitioners were consulted: 8 chiropractors, 5 medical doctors, 2 physical therapists, 1 osteopath, 1 acupuncturist, and 1 foot reflexologist
Compliance with interventions	High risk	Disconcordant compliance across the different therapies. Full compliance was noted for 90% (47/52) treated patients in the combined therapy group, 88% (43/49) treated patients in the joint manipulation group, 92% (47/51) treated patients in the myofascial therapy group, and 69% (33/48) treated patients in the back school group. The back school group was the least compliant
Timing of outcome assessments	Low risk	After 3 weeks of treatment and at 6 months follow-up.

Hurwitz 2002

Methods	RCT; adequate randomisation procedure
Participants	681 patients randomly allocated to 4 treatment groups; setting: health care network; conducted in California, USA; participants recruited during the period October 1995 to November 1998 Age (years) (mean (SD)): overall: 51.0 (16.7) Gender (% F): overall: 52% Inclusion criteria: eligible if 1) were health maintenance organization (HMO) members with the medical group chosen as their health care provider; 2) sought care from a health care provider on staff at one of the three study sites during the intake period; 3) presented with a complaint of low-back pain (defined as pain in the region of the lumbosacral spine and its surrounding musculature) with or without leg pain; 4) had not received treatment for low-back pain within the previous month; and 5) were at least 18 years old Duration LBP (total - for all 4 groups): 58.3% with symptoms longer than 3 months Exclusion criteria: if 1) had low-back pain resulting from fracture, tumour, infection, spondyloarthropathy, or other non-mechanical cause; 2) had severe coexisting disease; 3) were being treated by electrical devices (e.g., pacemaker); 4) had a blood coagulation disorder or were using corticosteroids or anticoagulant medications; 5) had progressive, unilateral lower limb muscle weakness; 6) had current symptoms or signs of cauda equina syndrome; 7) had plans to move out of the area; 8) were not easily accessible by telephone; 9) lacked the ability to read English; or 10) if their low-back pain involved third-party liability or workers' compensation
Interventions	1) Medical Care Only (N = 170). Consisted of one or more of the following at the discretion of the medical provider: instruction in proper back care and strengthening and flexibility exercises; prescriptions for pain killers, muscle relaxants, anti-inflammatory agents, and other medications used to reduce or eliminate pain or discomfort; and recommendations regarding bedrest, weight loss, and physical activities 2) Chiropractic Care Only (N = 169). Consisted of spinal manipulation or another spinal-adjusting technique (e.g., mobilization), instruction in strengthening and flexibility exercises, and instruction in proper back care. Chiropractic practice at the study site is consistent with chiropractic philosophy and training throughout the USA. The chiropractors routinely used the diversified technique, which is the general type of spinal manipulation taught in most chiropractic schools and is the most frequently used form of manipulation 3) Medical Care with Physical Therapy (N = 170). Patients assigned to this group received medical care as described above, instruction in proper back care from the physical therapist, plus one or more of the following at the discretion of the physical therapist: heat therapy, cold therapy, ultrasound, electrical muscle stimulation (EMS), soft-tissue and joint mobilization, traction, supervised therapeutic exercise, and strengthening and flexibility exercises. All physical therapy was administered in the medical group's physical therapy dept. and supervised by a licensed physical therapist 4) Chiropractic Care with Physical Modalities (N = 172). Patients assigned to this group received chiropractic care as described above plus one or more of the following at the discretion of the chiropractor: heat or cold therapy, ultrasound, and EMS The specific therapies received by patients varied within each treatment group, and our study protocol did not prescribe the type or amount of care that should be received by participating patients. Frequency of medical and chiropractic visits were at the discretion of the medical provider or chiropractor assigned to the patient. Frequency of physical

	therapy visits was at the discretion of the supervising physical therapist
Outcomes	Primary outcomes (as defined by the authors): Pain (11-point NRS, avg. and most severe pain in the past week); Back-pain specific functional status (Roland-Morris); complete remission (defined as the first observation during follow-up in which the above outcome variables were zero (i.e. no low-back pain in the past week and no related disability). Secondary outcome was perceived recovery (4-point scale - "a lot better", "a little better", "the same", and "worse"); adverse events - not reported Reported (but not listed as primary or secondary outcomes): frequency of pain and disability days, and use of medication across the groups Follow-up at 2 & 6 weeks, 6 months
Notes	Authors results and conclusions: The mean changes in LBP intensity and disability of participants in the medical and chiropractic care-only groups were similar at each follow-up assessment. Physical therapy yielded somewhat better 6-month disability outcomes than did medical care alone. After 6 months of follow-up, chiropractic care and medical care for LBP were comparable in their effectiveness. Physical therapy may be marginally more effective than medical care alone for reducing disability in some patients, but the possible benefit is small Funded by Agency for Healthcare Research and Quality (AHRQ) and the Southern California University of Health Sciences (Note: chiropractic college). The principal author was supported by a grant from the National Center for Complementary and Alternative Medicine (NCCAM) Principal author is a chiropractor and 2 of the 6 authors are chiropractors

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	The study statistician ran a computer program to generate randomised assignments in blocks of 12, stratified by site. The statistician placed each treatment assignment in a numbered security envelope. A separate series of sequentially numbered sealed envelopes was provided for each of the three sites
Allocation concealment (selection bias)	Low risk	When each patient consented to be in the study, the field coordinator opened the site-specific envelope in sequence and documented the patient for whom the assignment was made and the time of the assignment
Blinding (performance bias and detection bias) All outcomes - patients	High risk	There is no mention of attempts to blind the patients to other interventions or their perceptions of potential effectiveness of the different interventions

Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". Below includes the authors attempt at blinding the "outcomes assessor" Follow-up questionnaires mailed to the participants at the follow-up times, which addressed the primary and secondary outcomes
Incomplete outcome data (attrition bias) All outcomes - drop-outs	Low risk	At 2 wks (% retained): grp.1 - 100% (170/170); grp.2 - 100% (169/169); grp.3 - 99% (169/170); grp.4 - 99% (171/172) At 6 wks: grp.1 - 99% (169/170); grp.2 - 100% (169/169); grp.3 - 99% (168/170); grp.4 - 98% (169/172) At 6 months: grp.1 - 97% (165/170); grp. 2 - 98% (165/169); grp.3 - 94% (159/170) ; grp.4 - 95% (163/172)
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Low risk	No attempt was made to impute for missing values.
Selective reporting (reporting bias)	Low risk	No published protocol, but all primary outcomes (pain, functional status, and recovery) were reported
Group similarity at baseline	Low risk	
Influence of co-interventions	High risk	Approximately 20% of patients in the chiropractic groups received concurrent medical care, whereas 7% of patients in the medical groups received concurrent chiropractic care in the first 6 weeks. None of the chiropractic patients assigned to the chiropractic grp. only also received physical therapy, as opposed to approximately 3% of the medical patients assigned to receive medical care only who also received physical therapy
Compliance with interventions	High risk	The specific therapies received by patients varied within each treatment group and the study protocol did not prescribe the type or amount of care that should be received by participating patients. Frequency of medi-

Hurwitz 2002 (*Continued*)

		cal and chiropractic visits were at the discretion of the medical provider or chiropractor. Frequency of physical therapy visits was at the discretion of the supervising physical therapist Ninety-nine percent of patients had at least one visit to their assigned chiropractic or medical provider; however, about one-third of patients randomly assigned to medical care with physical therapy had no physical therapy visits
Timing of outcome assessments	Low risk	

Koes 1992

Methods	RCT; adequate allocation procedure
Participants	256 participants randomly allocated to 4 treatment groups; setting: private clinics of treating therapists and clinic of participating general practitioners; conducted in the Netherlands; participants recruited via an advertisement and those presenting to the GP; period of recruitment - January 1988 to December 1989 Age ((mean) years): overall: 43 Gender (% F): overall: 48% Inclusion criteria: participants with non-specific back and neck pain for at least 6 weeks; no physiotherapy or manipulative therapy had been received in the past two years for back and neck complaints; and the complaint could be reproduced by active or passive physical examination; no radiation below knee Duration present episode LBP (median, overall): 1 year Exclusion criteria: suspicion of underlying pathology (e.g. metastasis, osteoporosis, herniated disc); received physiotherapy or manual therapy for their back or neck complaints in the 2 yrs. prior; pregnancy; were unable to speak and read Dutch; or the complaints could not be reproduced by active or passive movements during the physical examination
Interventions	1) Manipulation and mobilization (according to directives of the Dutch Society for Manual Therapy = physiotherapists trained in manipulative techniques) (N = 65): 7 manual therapists involved; no. tx: average 5.4, mean duration tx: 8.9 weeks 2) Physiotherapy (N = 66): consisting of exercises, massage, heat and electrotherapy; the majority of patients received exercise and massage; 8 physiotherapists involved; no. tx: average 14.7, mean duration tx: 7.8 weeks 3) Placebo (N = 64): consisting of detuned short-wave diathermy and detuned ultrasound; no. tx: average 11.1, mean duration tx: 5.8 4) General practitioner (N = 61): consisting of advice about posture, analgesics, exercises, participation in sports, bed rest, etc; 40 GP's involved; no. tx: 1 After 6 wks, the patients returned to the GP with a written report from the MT or PT in order to discuss the results and to decide whether the tx. should be continued or altered. All treatments were given for a maximum of 3 months

Koes 1992 (*Continued*)

Outcomes	According to the authors in the sequence of importance (outcomes were not defined as primary or secondary): Severity of the complaint (10-point scale, measured by a blinded research assistant and consisted of scored based upon the anamnese and physical exam) ; global perceived effect (6 point scale, presented as a continuous variable); pain (West Haven-Yale Multidimensional Pain Inventory, 6 point sub-scale); generic functional status (Sickness Impact Profile); spinal mobility and physical functioning (degrees); adverse events - not reported Follow-up: 3, 6, 12, 26 & 52 weeks
Notes	Authors results and conclusions: Both physiotherapy and manual therapy decreased the severity of complaints more and had a higher global perceived effect compared to continued treatment by the GP. Differences in the effectiveness between physiotherapy and manual therapy could not be shown Funded by Dutch Ministry of Welfare, Health and Cultural Affairs Principal author is epidemiologist. LBP data was provided from Gert Bronfort.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomization per stratum occurred by use of list of random numbers. Prestratification by location of the complaint and residence was further carried out to prevent unequal distribution. Within each stratum, the random assignment was performed in blocks of eight
Allocation concealment (selection bias)	Low risk	Randomization was carried out be a second research assistant
Blinding (performance bias and detection bias) All outcomes - patients	High risk	Patients were blinded to the placebo therapy only, but not blinded to the other therapies
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". Below includes the authors attempt at blinding the "outcomes assessor" Physical functioning (e.g. range of motion) was assessed by a research assistant, blinded to treatment allocation and to the previous scores

Koes 1992 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes - drop-outs	Low risk	At 3 wks (% retained): grp.1: 98% (64/65); grp. 2 - 97% (64/66); grp.3 - 92% (59/64); grp.4 - 93% (57/61) At 6 wks: grp.1: 98% (64/65); grp.2 - 94% (62/66); grp.3 - 91% (58/64); grp.4 - 90% (55/61) At 12 wks: grp.1: 95% (62/65); grp.2 - 92% (61/66); grp.3 - 88% (56/64); grp.4 - 89% (54/61) At 6 mos: grp.1: 89% (58/65); grp.2 - 83% (55/66); grp.3 - ?; grp.4 - ? At 12 mos: grp.1: 85% (55/65); grp.2 - 74% (49/66); grp.3 - ?; grp.4 - ?
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Low risk	
Selective reporting (reporting bias)	High risk	No published protocol available; back-pain specific functional status not examined
Group similarity at baseline	Low risk	
Influence of co-interventions	High risk	Contamination and co-interventions mainly occurred among patients in the placebo and general practitioner grp. Seven patients in the placebo grp. received physiotherapy before the 3-week follow-up; one due to an administrative error, one due to unmasking of the placebo by the patient, and 5 because the therapist decided that giving the placebo was not appropriate for the patient in question 4 patients in the GP grp. received physiotherapy or manual therapy before the 3-week follow-up; one because the patient did not want treatment by the GP, one because the GP carried out manual therapy himself, and two because the GP thought that a referral was more appropriate At the 6-week follow-up, these figures appeared to be slightly higher. Between the 6- and 12-week follow-up, a considerable number of patients in the placebo and GP grp. changed from the assigned therapy In the physiotherapy and manual therapy grp., these changes occurred considerably less often
Compliance with interventions	Unclear risk	All therapists were free to choose from their usual therapeutic domains and prescribe TX plans. Unclear how many txs were prescribed
Timing of outcome assessments	Low risk	

Licciardone 2003

Methods	RCT; allocation not properly performed.
Participants	91 patients randomly allocated to 3 treatment groups; setting: university-based osteopathic clinic in USA; recruitment - January 2000 to February 2001 using advertising in local newspapers and referrals from university-based clinics and from other local physicians Age (mean in years (SD)): grp. 1 - 49(12); grp. 2 - 52(12); grp. 3 - 49(12) Gender (%F): grp. 1 - 69; grp. 2 - 57; grp. 3 - 65 Included if: constant or intermittent, non-specific low-back pain for at least 3 months, between 21-69 years of age; subjects with sciatica were included only if they tested negative for all of the following: 1) ankle dorsiflexion weakness; 2) great toe extensor weakness; 3) impaired ankle reflexes; 4) loss of light touch sensation in the medial, dorsal, and lateral aspects of the foot; 5) ipsilateral straight-leg-raising test (positive result: leg pain at 60°); 6) crossed straight-leg raising test (positive result: reproduction of contralateral pain) Duration LBP: range - 39% to 63% with LBP > 1 yr. Excluded if: specific causes of LBP (e.g. fracture, herniated disc, cauda equina, spinal osteomyelitis); surgery on the low-back within the preceding 3 months; receiving workers' compensation or involved in litigation related to the low-back; pregnant; former patient or employee of the trial clinic site; undergone spinal manipulation in the preceding 3 months or on more than three occasions in the preceding year
Interventions	1) Orthomanual (or osteopathic) therapy (OMT) (N = 48) - sessions lasted 15 to 30 minutes, and the OMT was performed by pre-doctoral osteopathic manipulative medicine fellows. The techniques included one or a combination of the following: myofascial release, strain-counterstrain, muscle energy, soft tissue, high-velocity-low-amplitude thrusts, and cranial-sacral. The OMT was aimed at somatic dysfunction in the low back or adjacent areas 2) Sham manipulation (N = 23) - subjects received treatments according to the same protocol and timetable as OMT group. Treatment included range of motion (ROM) activities, light touch, and simulated OMT techniques. This latter consisted of manually applied forces of diminished magnitude aimed purposely to avoid treatable areas of somatic dysfunction and to provide minimal likelihood of therapeutic effect 3) No-intervention control (N = 20) - allowed to receive usual care (Comment: There was no personal interaction with the no-intervention control group after the baseline assessment, data collection, and randomisation (personal communication with the primary author)) Osteopathic and sham manipulation subjects were treated for a total of seven visits over 5 months, including visits at 1 week, 2 weeks, and 1 month after baseline assessment, and then monthly thereafter All subjects regardless of grp. assignment were allowed to receive usual or other low-back care to complement the trial interventions, with the exception of other OMT or chiropractic manipulation
Outcomes	Primary outcome measures (as determined by the authors): Pain: VAS (0 to 10cm); Back-pain specific functional status: Roland-Morris; Generic health status: SF-36; lost work or lost school days due to LBP; number of co-treatments; current back-pain specific medication use; global satisfaction w/ the care; 8 of the sub-scales from the SF-36 were considered among the primary outcomes (e.g. physical functioning, bodily pain, general health, vitality, etc); recovery - not reported; adverse events - not reported

	Follow-up: 1, 3, 6 months
Notes	Authors results and conclusions: OMT and sham manipulation both appear to provide some benefits when used in addition to usual care for treatment of chronic nonspecific LBP. It remains unclear whether the benefits of OMT can be attributed to the treatment techniques or other aspects of the treatment Funded by American Osteopathic Association. 5 of the 6 authors, including the principal author are osteopaths Primary author was contacted for data on VAS and RMDQ at the various follow-up measurements that was not clearly reported in the article - this data was received. Pre-doctoral fellows may not have had sufficient practical experience to provide OMT w/ the same efficacy as more seasoned practitioners or to provide non-therapeutic sham manipulation; low baseline RMDQ scores

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomization was performed using sequential sealed envelopes prepared by the clinical research technician before enrolment of the subjects. The subjects were assigned randomly to one of three treatment groups in an approximate 2:1:1 ratio: OMT, sham manipulation, or no intervention as a control condition. The intent of this allocation strategy was to enrol comparable numbers of subjects receiving OMT and not receiving OMT, and subsequently to combine the sham manipulation and no-intervention control groups should no statistically significant differences be observed between the latter groups
Allocation concealment (selection bias)	Unclear risk	The treating pre-doctoral osteopathic manipulative medicine fellows subsequently opened the sealed envelopes and recorded the allocation of subjects as they entered the trial. All trial personnel with the exception of the osteopathic fellows were blinded to treatment group assignments throughout the trial. Note: Unclear, but appears that those who determined allocation were also involved in the actual treatment
Blinding (performance bias and detection bias) All outcomes - patients	Unclear risk	Subjects assigned to sham manipulation were blinded to the therapy; however, no mention by the authors of post-treatment evaluation of the success of blinding by the

		patients (comment: confirmed via contact with the principal author). The authors do mention that they tried to ensure that the protocol for the real and sham treatment were carried out as prescribed
Blinding (performance bias and detection bias) All outcomes - providers	High risk	Care providers were not blinded.
Blinding (performance bias and detection bias) All outcomes- outcome assessors	Unclear risk	Unclear blinding of the patient; therefore, here it is unclear All trial personnel, with the exception to the osteopathic fellows, were blinded to treatment group assignments throughout the trial. In the no-intervention control group, follow-up was via postal questionnaires and not during a visit to the clinic (as opposed to the other treatment groups). No post-treatment interview (or questionnaire) was conducted to assess success of blinding by the patients
Incomplete outcome data (attrition bias) All outcomes - drop-outs	High risk	At 1 month (% retained): OMT (42/48) = 88%; sham (23/23) = 100%; control (17/20) = 85% at 3 months: OMT (36/48) = 75%; sham (19/23) = 83%; control (16/20) = 80% at 6 months: OMT (32/48) = 67%; sham (19/23) = 83%; control (15/20) = 75% No explanations were offered for individuals that dropped-out
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Unclear risk	Not stated and no attempt was made to impute for missing cases
Selective reporting (reporting bias)	High risk	(According to the authors) 14 primary outcomes: Pain (10-cm VAS); Back-pain specific functional status: Roland-Morris; SF-36 (8 sub-scales, incl. physical functioning, role limitations - physical & emotional, bodily pain, general health, vitality, social functioning, and mental health); number of co-treatments, current back pain-specific medication use, lost work or school days related to back pain, and global satisfaction with back care. Recovery was not reported No published protocol was available and the authors note 14 primary outcomes, thus no

		a priori decision was made regarding which were primary and secondary, leading to potential reporting bias of those outcomes that were significant
Group similarity at baseline	Low risk	
Influence of co-interventions	Low risk	All the subjects, regardless of group assignment, were allowed to receive usual or other low-back care to complement the trial interventions, with the exception of other OMT or chiropractic manipulation. Data were collected on each subject's use of co-treatments throughout the trial including prescription and over-the-counter medications, physical therapy, massage therapy, hydrotherapy, transcutaneous electrical nerve stimulation, spinal and epidural injections, acupuncture, herbal therapies, and meditation. However, the OMT subjects used significantly fewer co-treatments than the no-intervention control subjects at 6 months. There were no significant differences among the treatment groups in back-pain specific medication use or lost work or school days over time (Comment: Co-intervention use was assessed only at baseline, 1 and 6 months, asking about such use during the 4 previous weeks. The 1-month assessment probably did not provide sufficient time following randomisation to make appointments with clinicians, clinics, hospitals, etc. outside the trial protocol. Whereas by 6 months, subjects had more time to acquire such co-treatments (personal communication with the primary author).)
Compliance with interventions	Unclear risk	Unclear if (or what percentage of) the subjects assigned to OMT or sham manipulation attended the number or sessions prescribed in the methods
Timing of outcome assessments	Low risk	

Mohseni-Bandpei 2006

Methods	RCT; unclear allocation procedure.
Participants	120 patients randomly allocated to 2 treatment groups; setting: outpatient physical therapy department in Norfolk and Norwich Hospital, United Kingdom; period of recruitment not stated Age: manipulation/exercise grp 34.8 (10.6); ultrasound/exercise grp 37.2 (10.2) Gender (% F): grp.1 - 61%; grp. 2 - 57% Included if: between 18 and 55 years with LBP between L1 and L5 and the sacroiliac joints; LBP >3 months duration, signs and symptoms that were interpreted as referred from the lumbar spine and not other organs; good self-reported general health; and were literate in the English language Duration of current LBP (mean (SD) in months): grp. 1 - 35.9 (48.3); grp. 2 - 50.8 (62. 9) Radiation pattern of pain: unclear. Excluded if: underlying disease, such as malignancy; obvious disc herniation, osteo-porosis, viscerogenic causes, infection or systemic disease of the musculoskeletal system; previous SMT or ultrasound treatment; neurologic or sciatic nerve root compression, radicular pain, sensory disturbances, loss of strength and reflexes; previous back surgery; evidence of previous vertebral fractures or major structural abnormalities; tumour of the spine; pregnancy; devices such as heart pacemakers; or registered disabled or receiving benefits because of LBP
Interventions	1) SMT + exercise (N = 60) - Maitland technique; high-velocity low-amplitude thrust on lumbar spine and SI joint. On average each patient was treated for 4 sessions (range 2 to 7 sessions), once or twice per week 2) ultrasound + exercise (N = 60): 1 MHz; on average each patient was treated for 6 sessions (range 3 to 11 sessions), once or twice per week Exercise as recommended by Schneiders et al. Patients were given a written set of exercises generated by PhysioTools computer package, which is available in most physiotherapy departments in the UK. The physiotherapist chose exercises most appropriate for each individual patient's condition
Outcomes	Pain: 100-mm VAS; Back-pain specific functional status: Oswestry; Lumbar range of motion (ROM), surface EMG, muscle endurance; recovery - not reported; adverse events - not reported; (comment: Outcomes not defined as primary or secondary by the authors) Follow-up: post-treatment (6 weeks), 6 months - mean group differences presented only
Notes	Funded by: Islamic Republic of Iran Ministry of Health and Medical Education (Mazan-daran University of Medical Sciences) Principal author: medical doctor Authors results and conclusions: Although improvements were recorded in both inter-ventions, patients receiving manipulation + exercise showed greater improvement com-pared with those receiving ultrasound + exercise at both the end of treatment and at six months follow-up

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Mohseni-Bandpei 2006 (*Continued*)

Random sequence generation (selection bias)	Unclear risk	The participants who met the inclusion and exclusion criteria were assigned a number according to a block-style randomisation scheme
Allocation concealment (selection bias)	Unclear risk	Note: no other information was provided on the sequence generation or allocation
Blinding (performance bias and detection bias) All outcomes - patients	High risk	There is no mention of attempts to blind the patients to other interventions or their perceptions of potential effectiveness of the different interventions
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as ”no“. Below includes the authors attempt at blinding the ”outcomes assessor“ An assessor blinded to treatment allocation conducted an assessment of both subjective (pain, functional status) and objective outcomes (lumbar range of motion, surface EMG, and muscle endurance)
Incomplete outcome data (attrition bias) All outcomes - drop-outs	High risk	Follow-up post-treatment (% retained): grp.1 - 93% (56/60); grp.2 - 93% (56/60) At 6 months: grp.1 - 67% (40/60); grp.2 - 55% (33/60) Note: 8 patients dropped-out during the treatment phase for various reasons, ranging from family problems to psychological problems, moving residence, loss of contact. No reasons were given regarding loss to follow-up during the post-treatment phase
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Unclear risk	Not stated.
Selective reporting (reporting bias)	High risk	Recovery not reported; no published protocol was available.
Group similarity at baseline	Low risk	
Influence of co-interventions	Unclear risk	The physiotherapist chose exercises most appropriate for each individual patient's condition; therefore, it is also unclear to what extent these were similar between groups. Patients were al-

Mohseni-Bandpei 2006 (*Continued*)

		lowed to continue with their medication (i.e. pain killers, non-steroidal anti-inflammatory drugs, muscle relaxants)
Compliance with interventions	Unclear risk	Not stated.
Timing of outcome assessments	Low risk	

Muller 2005

Methods	RCT; adequate treatment allocation
Participants	115 patients randomly allocated to 3 treatment groups; setting: multidisciplinary spinal pain unit of a general hospital in Queensland, Australia; recruited from February 1999 to October 2001 Age: overall 39 (IQR 29-46); grp. 1- 39 (29-53); grp. 2 - 38 (27-47); grp. 3 - 39 (26-43) Gender (% F): overall: 46.8%; grp.1 - 52.2%; grp. 2 - 45%; grp. 3 - 42.1% Included if: uncomplicated mechanical spinal pain $\geq$ 13 weeks, > 17 years of age. Duration of the current LBP (median (IQR)): grp.1 - 4 to 12 months (range: 4 mos. to 45 yrs); grp.2 - 4 to 12 months (range: 4 mos. to 20 yrs); grp.3 - 1 to 5 years (range: 4 mos. to 30 yrs) Excluded if: nerve root involvement, spinal anomalies other than sacralisation or lumbarisation, pathological conditions other than mild-moderate osteoarthrosis, > grade 1 spondylolisthesis of L5 on S1, previous spinal surgery, or leg length inequality of > 9mm.
Interventions	1) SMT (N = 36): High-velocity low-amplitude spinal manipulative thrust to a joint 10,18 was performed as judged safe and usual treatment by the treating chiropractor for the spinal level of involvement to mobilize the spinal joints at that level 2) Acupuncture (N = 36): Acupuncture was performed using sterile HWATO Chinese Acupuncture Guide Tube Needles (50 mm long; 0.25-mm gauge) for 20-minute appointments. For each patient, 8 to 10 needles were placed in local paraspinal intramuscular maximum pain areas, and approximately 5 needles were placed in distal acupuncture point meridians (upper limb, lower limb, or scalp). Once patients could satisfactorily tolerate the needles, needle agitation was performed by turning or "flicking" the needles at approximately 5-minute intervals. Needles were placed in local paraspinal pain areas and in distal acupuncture point meridians; treatment frequency was the same as defined above for SMT 3) Medication (NSAIDs or paracetamol) (N = 43): Celecoxib (Celebrex) (200 to 400 mg/d; 27 patients) unless celecoxib had previously been tried; the next drug of choice was rofecoxib (Vioxx) (12.5 to 25 mg/d; 11 patients), followed by acetaminophen (paracetamol) (500 mg tablets 2 to 6 per day; 5 patients). Dosage followed pharmaceutical guidelines The frequency and duration of the manipulation and acupuncture were standardized in order to account for potential placebo effects originating from different lengths of exposure to the treating clinician, namely two 20-minute office visits per week until patients became asymptomatic or achieved acceptable pain relief

Muller 2005 (*Continued*)

Outcomes	Pain: visual analogue scale (VAS; 0 to 10cm); Back-pain specific functional status: Oswestry; generic health status: SF-36; straight-leg raising; active range of motion for the lumbar and cervical spines; recovery - not reported; adverse events - 6% in the medication grp. had an adverse reaction - presumably none in the manipulation grp., but this is not clearly stated by the authors; (comment: Outcomes not defined as primary or secondary outcomes by the authors.) Follow-up: 4 & 9 weeks, 12 months
Notes	Authors results and conclusions: In patients with chronic spinal pain syndromes, spinal manipulation may be the only treatment modality of the assessed regimens that provides both broad and significant long-term benefit Funded by Queensland State Government Health Dept., and supported by the Townsville Hospital Unclear what proportion of patients with low-back pain; possibly biased by high and differential rates of drop-out between the groups and crossover contamination; results presented in median and IQR; earlier publications Giles 1999, Giles 2003. The neck was also examined in this study and outcomes relating to this area were also measured. Four week data reported in Giles 1999 Considered to have a fatal flaw due to the differential and large proportion of drop-outs, especially for the acupuncture group at the short-term and medication group at the long-term measurement One of the 2 authors is a chiropractor (Giles).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	After informed written consent had been obtained, the patients were randomised in a balanced way
Allocation concealment (selection bias)	Unclear risk	Each patient drew a sealed envelope from a box with 150 well-shuffled envelopes containing one of three possible treatment codes so that an efficacy comparison could be made between three active treatments. Comment: no other text was provided in any of the other publications regarding the randomisation and allocation procedure. It is not clear if the person involved in the randomisation procedure was an independent research assistant; thus, unclear what safeguards were in place, for example
Blinding (performance bias and detection bias) All outcomes - patients	High risk	"It was not possible to blind the treating or non-treating clinicians"

Blinding (performance bias and detection bias) All outcomes - providers	High risk	"It was not possible to blind the treating or non-treating clinicians"
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". Below includes the authors attempt at blinding the "outcomes assessor" All the outcome assessments were performed exclusively by the research assistant providing subjective questionnaires and performing objective measurements, except for an additional assessment for patients who experienced early recovery or an adverse reaction. Such additional assessment was performed by a non-treating clinician. The individual endpoint of the study was defined as either early recovery (symptoms no longer present at the week 2 or week 5 assessment) or the final assessment at week 9, whichever occurred earlier
Incomplete outcome data (attrition bias) All outcomes - drop-outs	High risk	At 4 weeks (% retained): grp.1 - 74%; grp.2 - 48%; grp.3 -80% (Quote: "The proportion of drop-outs in the treatment groups differed significantly with respect to the interventions". Comment: The number of subjects presented in the results are confusing from the pilot study (Giles 1999). According to this, the drop-outs were 36% for SMT and 48% for medication. The numbers for acupuncture cannot be correct because it states that 26 subjects dropped out of the acupuncture grp, but just 20 were randomised to this group.) At 9 wks (% retained): grp. 1 - 69% (25/36); grp. 2 - 61% (22/36); grp. 3 - 51% (22/43); overall - 60% (69/115) At 12 mos (% retained): grp. 1 - 64% (23/36) ; grp. 2 - 56% (20/36); grp. 3 - 44% (19/43); overall - 54% (62/115) Reasons for drop-outs varied among the groups. More subjects changed treatment at wk.9 for the medication grp. *versus* the SMT grp. (23% vs. 6%)
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	High risk	An ITT and per-protocol analysis was conducted; however, the ITT analysis was conducted on a very limited data set given the large percentage of drop-outs, for example 54% (62/115) at 12 mos

Muller 2005 (*Continued*)

Selective reporting (reporting bias)	High risk	No published protocol available; recovery not reported.
Group similarity at baseline	Low risk	
Influence of co-interventions	Unclear risk	Not stated.
Compliance with interventions	High risk	Differential and large degree of drop-out from the study; "During patient tracking, it was found that 22 patients received, at some stage after their study treatment period but within the extended follow-up period, a different treatment from the randomised regimen"
Timing of outcome assessments	Low risk	

Paatelma 2008

Methods	RCT; unclear allocation procedure
Participants	134 patients randomly allocated to 3 treatment groups; recruited from 4 occupational health care centres in Jyvaskyla, Finland; occupational physicians identified the eligible subjects; period of recruitment not reported Age (mean (SD)): grp. 1 - 44 (10); grp. 2 - 44 (9); grp. 3 - 44 (15); no overall age reported Gender (% F): grp.1 - 42%; grp. 2 - 29%; grp. 3 - 35% Inclusion criteria: 18 to 65 years of age, employed, with current non-specific LBP with or without radiating pain to one or both lower legs; no restrictions on duration or recurrence of the LBP Duration of the LBP: Personal communication with the primary author: Slightly more than 50% were defined as chronic by the authors Exclusion criteria: pregnancy, low-back surgery less than 2 months previously, red flag indicating serious spinal pathology
Interventions	1) OMT (orthopedic manual therapy) (N = 45): includes spinal manipulation, specific mobilization, and muscle-stretching techniques; high-velocity, low-force techniques were used, including prone or side-lying manipulation to L1 to L5 and sacro-iliac manipulation or mobilization. Patients were taught to perform self-mobilisation, stretching and exercises at home daily 2) McKenzie (N = 52): subjects were assessed and classified into the various mechanical syndromes, which was subsequently selected as the treatment strategy; this consisted of education supported by the book "Treat your own back", and an active therapy component (exercises to be repeated several times per day, every 1 to 2 hours, on a regular basis) 3) Advice-only (N = 37): 45 to 60 min. counselling from a physiotherapist concerning the good prognosis of LBP and concerning pain tolerance, medication usage, and return-to-work. Patients were told to avoid bed rest, and advised to continue their routine as actively as possible, incl. exercise activities. A 2-page educational booklet was also supplied

Paatelma 2008 (*Continued*)

	The advice group received just one visit and the number of visits for the OMT and McKenzie grp. ranged from 3 to 7 (mean: 6 txs per group)
Outcomes	Pain: back and leg pain (VAS, 0 to 100); Back-pain specific functional status: Roland-Morris; recovery - not reported; adverse events - not reported; (comment: Outcomes were not defined as primary or secondary by the authors) Follow-up: at 3, 6 & 12 months
Notes	Authors results and conclusions: No differences emerged between the orthopaedic manual therapy and McKenzie method grp. for pain or functional status at any follow-up measurement. OMT and McKenzie seem to be only marginally more effective than one session of assessment and advice only Funded by: not stated. Primary author is physiotherapist and 4 of the 6 authors were physiotherapists (2 were medical doctors)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	randomisation was by a stack of sealed envelopes, numbered in an order prepared from a random number table. Note: no other text was available
Allocation concealment (selection bias)	Unclear risk	Unclear if the sealed envelopes were opaque or not and whether an independent examiner was involved in the actual allocation procedure
Blinding (performance bias and detection bias) All outcomes - patients	High risk	There is no mention of attempts to blind the patients to other interventions or their perceptions of potential effectiveness of the different interventions
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". No mention of trying to blind the outcomes assessor
Incomplete outcome data (attrition bias) All outcomes - drop-outs	High risk	High drop-out rate among the advice-only group. Follow-up (% retained) at 3 months: OMT (43/45 = 96%); McKenzie (48/52 = 92%); Advice-only (29/37 = 78%) At 6 months: OMT (40/45 = 89%); McKenzie (47/52 = 90%); Advice-only (27/37 = 73%) At 12 months: OMT (35/45 = 78%); McKenzie (45/52 = 87%); Advice-only (26/37 = 70%)

Paatelma 2008 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Low risk	missing values were replaced with imputed values generated by the subjects' previous scores
Selective reporting (reporting bias)	High risk	recovery not reported; no published protocol available.
Group similarity at baseline	Low risk	
Influence of co-interventions	Unclear risk	Co-interventions were not allowed by design, but unclear whether subjects actually sought other care (not examined or not reported)
Compliance with interventions	Unclear risk	not reported
Timing of outcome assessments	Low risk	At 3, 6, 12 months

Pope 1994

Methods	RCT; unclear allocation procedure
Participants	164 subjects allocated to chiropractic treatment/manipulation, massage, corset, and transcutaneous muscle stimulation; recruited via a chiropractic college (Whittier Health Center at the Los Angeles College of Chiropractic) and via additional advertising (e.g. radio, newspaper, flyers); period of recruitment unclear Age: 32 years (median age - for the entire group), 72% were under 40 years of age, 8% were $\geq$ 50 years of age Gender: 38% F (entire group) - not listed separately per intervention Inclusion criteria: 18 to 55 years of age; current LBP between 3 weeks to 6 months duration and preceded by a period of 3 weeks without LBP; generally good health (self-reported); not pregnant; no sciatica (defined by pain below the knee, a positive straight leg raising test, and neurologic deficit, including subjects with buttock and upper thigh pain); no neurological deficits, such as loss of sensation, strength and reflex; no previous vertebral fracture, tumour, infection or spondyloarthropathy; no previous back surgery; Davenport weight index not greater than 33 (wt/ht^2, units kg and m); no previous manipulative therapy for this episode; no conditions potentially aggravated by electrical devices (i.e. heart pacemaker); no workmen's compensation or disability insurance issues; willing to travel to the facility for treatment and to be randomised Duration current episode of LBP: 29% < 6months, 35% between 6 months & 2 years, 36% longer than 2 years Exclusion criteria: not explicitly defined.
Interventions	1) spinal manipulation (N = 70): subject was placed in side-lying position with the side of the manipulable lesion most superior from the table surface. Once the end of the physiologic range of motion was achieved, a dynamic short-lever high-velocity low-amplitude thrust was applied exerting a force on the lumbar spine and/or sacroiliac joint. This maneuver was performed unilaterally or bilaterally at each treatment session as determined by the treating physician. Frequency of treatment sessions was 3 times per week for 3 weeks. Full-compliance was defined as receiving 3 or more sessions per week,

	with partial compliance defined as 1-2 sessions per week, and no compliance defined if subjects received no sessions. 5 licensed chiropractors delivered the manipulations to the patients. No statement provided on level of experience 2) soft-tissue massage (N = 37): effleurage was provided with the patient in the prone position on a chiropractic table; smooth non-forceful motions were used; the skin of the back from the buttocks to the shoulders was rubbed in a rhythmic fashion. The time for treatment did not exceed 15min. and the number of treatment sessions for the 3-week period was the same as for spinal manipulation (as listed above). 2 licensed massage therapists, delivered by chiropractic interns, provided these treatments 3) transcutaneous muscle stimulation (TMS) (N = 28): patients were fitted with the Myocare PLUS muscle stimulating unit that was programmed for continuous use. A biphasic pulse rate was used and the amplitude was set at a maximum of 91mA. Four TMS electrodes were placed on the back in the area around the pain. Placement of the electrodes was linear. Patients were instructed to wear the TMS unit for a cumulative total of at least 8 hrs./day for a minimum of 1 hour at a time. Full compliance was a minimum of 7 hrs./day on average, partial compliance was a minimum of 4 to 7 hrs./day and no compliance was < 4 hrs./day 4) corset (N = 29): patients were measured and fitted for a Freeman Lumbosacral Corset by a trained clinician. The corset is a canvas corset with metal stays in the back. The patient was instructed to wear the corset during waking hours, except when bathing. Further, the patient was allowed to remove the corset for a maximum of 10 min. at a time, up to three times per day A chiropractor instructed and monitored the use of the corset and TMS units. Compliance was measured by a diary maintained by the subject with the same hourly usage figures as for TMS
Outcomes	Pain: 10 cm. VAS (converted to a 0 to 100 numerical scale); Back-pain specific functional status: not reported; Recovery: not reported; adverse events: not reported; additional outcomes: range of motion (Schober's test), maximum voluntary extension effort, Sorensen Fatigue Test (via EMG monitoring). (Outcomes were not defined as primary or secondary.) Follow-up: weekly for 3 weeks.
Notes	Authors results and conclusions: After three weeks, the manipulation group scored the greatest improvements in flexion and pain while the massage group had the best extension effort and fatigue time, and the muscle stimulation group the best extension. Non of the changes in physical outcome measures (ROM, pain, fatigue, strength) were significantly different between any of the groups Funded by:Foundation for Chiropractic Education and Research Primary author is a researcher at the Iowa Spine Research Center, University of Iowa; 3 of the 6 research members are chiropractors

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"....Patients were assigned a number according to a block-style randomisation scheme." No information was provided as to how the numbers were

Pope 1994 (*Continued*)

		generated nor whether allocation was concealed
Allocation concealment (selection bias)	Unclear risk	Not stated.
Blinding (performance bias and detection bias) All outcomes - patients	High risk	There is no mention of attempts to blind the patients to other interventions or their perceptions of potential effectiveness of the different interventions
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". Outcomes assessors were blinded to allocation and collected data on the primary outcomes (e.g. pain, function, etc)
Incomplete outcome data (attrition bias) All outcomes - drop-outs	Low risk	88% follow-up at the final assessment (3 weeks) . The dropout rates were not significantly different between the 4 groups, but were lowest for the manipulation group (6% vs. 14 to 21%). No description on the reason for dropout was provided. No sensitivity analysis was conducted comparing baseline values between subjects who completed the study and those who did not
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Unclear risk	Not stated.
Selective reporting (reporting bias)	High risk	Back-pain specific functional status and recovery not reported; no available protocol published
Group similarity at baseline	Low risk	Testing of the primary outcome factors at baseline, as well as certain other background factors (e.g. number of previous LBP incidents, length of current LBP episode, job status, pain level) indicate that there were no statistically significant differences among the treatment groups, except in one case. The mean confidence (0 to 10) that their proposed care would work was significantly higher at the first visit in the manipulation group (7.7) than in the TMS (6.4) or corset (6.0) groups, based on Tukey's studentized range test for means ($P < 0.05$) While potentially clinically relevant, this one factor was not thought to appreciably offset the overall judgement of the reviewers' assessment of this criterion

Pope 1994 (*Continued*)

Influence of co-interventions	Unclear risk	Not stated.
Compliance with interventions	Low risk	The rates for completing all 4 visits are not significantly different (64% to 79% among the treatment groups), but are lowest in the TMS group. There was no statistically significant difference in compliance among the 4 treatments. At the fourth evaluation, the percentages for full compliance were 38% for SMT, 47% for massage, 50% for TMS, and 65% for corset groups. For the TMS group, 27% of the 22 rated did not comply at all; for SMT, 21% did not comply; for massage, 10% did not comply; and for the corset group, 6% did not comply at all
Timing of outcome assessments	Low risk	For all groups, weekly for 3 weeks.

Postacchini 1988

Methods	RCT; allocation procedure unclear
Participants	459 patients randomly allocated to 6 treatment groups; setting: 2 low-back pain clinics (university orthopaedic clinic and a "Static Center" of Rome) between January 1985 - October 1986; setting: hospital outpatient department; conducted in Italy Age (mean (years)): grp.1B - 38.4; grp. 2B - 39.5 Gender (% F): grp.1B - 51% (39/77); grp. 2B - 49% (39/80) Inclusion criteria: low-back pain, aged 17 to 58 years. Pattern of pain radiation: with and without radiation below knee; 2 groups - acute (< 4 weeks) and chronic (> 9 weeks) LBP Duration of the current LBP (mean): grp. 1B - 13 months; grp. 2B - 9 months (all other grps. are not relevant for this report) Exclusion criteria: Pregnancy or nursing women, serious general diseases, psychiatric disturbances, medico-legal litigation
Interventions	Two principal grps: grp.1 - LBP only; grp. 2 - LBP radiating to the buttocks and/or thighs and no neurological changes Subgrps. were defined as: A - LBP <4 wks. duration and no LBP in the preceding 6 months; B - continuous or almost continuous LBP lasting more than 2 months; C - chronic LBP with an episode of acute pain at the time of clinical observation 1) Manipulation by trained chiropractor (at follow-up: N = 87); no. tx chronic patients: 12; at a rate of 2 tx per week 2) Diclofenac "full dose" (at follow-up: N = 81); duration tx: 2 weeks 3) Physiotherapy: massage, electrotherapy, infrared, etc. (at follow-up: N = 78); no. tx: 15, daily for 3 weeks 4) Bed rest (at follow-up: N = 29); duration tx: 6 to 8 days 5) Back school (at follow-up: N = 50); no. tx: 4 in 1 week 6) Placebo gel (at follow-up: N = 73); duration 1 or 2 weeks

Postacchini 1988 (*Continued*)

Outcomes	Pain (4-point scale: ranging from none to most severe pain imaginable); Back-pain specific functional status (4-point scale: extremely, moderately, slightly or not limited); spinal mobility (forward flexion: fingertip to floor distance); abdominal muscle strength (assessed by the leg-lowering test, and isometric endurance); recovery - not reported; adverse events - not reported. Evaluation was based upon a sum score including both subjective and objective measures. Comment: Outcomes not defined as primary or secondary by the authors Follow-up: 3 weeks, 2 & 6 months
Notes	Authors results and conclusions: In subgrp.1B, the best results were obtained with physiotherapy at short-term and low-back school at the long-term. For subgrp.2B, physiotherapy gave the best results at both short- and long-term follow-up Funded by: grant from the Centro Studi di Patologia Vertebrale, Rome Principal author is an orthopedist? Unequal numbers for the intervention grps. because not all interventions applied to the various groups (acute - chronic)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Patients in each grp. were randomly assigned to the following treatments
Allocation concealment (selection bias)	Unclear risk	Note: No other information was provided on the sequence generation or allocation
Blinding (performance bias and detection bias) All outcomes - patients	High risk	There is no mention of attempts to blind the patients to other interventions or their perceptions of potential effectiveness of the different interventions
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". No mention if there were any attempts to blind the outcome assessors to treatment allocation for the subjective or objective outcome measures
Incomplete outcome data (attrition bias) All outcomes - drop-outs	Unclear risk	Not stated.
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	High risk	13% of those randomised were either lost to follow-up or changed their assigned treatment and subsequently not included in the analyses

Postacchini 1988 (*Continued*)

Selective reporting (reporting bias)	High risk	No published protocol available; recovery not reported.
Group similarity at baseline	Unclear risk	Similar for the 2 grps. with chronic LBP (based upon age, gender, and duration of symptoms), but unclear for the baseline scores for functional status
Influence of co-interventions	High risk	8% (38/459) of the subjects had interrupted or changed their assigned treatment
Compliance with interventions	Unclear risk	Not stated.
Timing of outcome assessments	Low risk	

Rasmussen 2008

Methods	RCT; unclear allocation procedure
Participants	72 patients randomly allocated to 2 treatment groups; setting: dept. of rheumatology in Frederiksberg Hospital, Denmark; patients were referred from general practitioners; period of recruitment - "one year" Age (years): grp. A (with SMT): 38 (range: 26 to 57); grp. B (no SMT): 42 (range: 27 to 65); no data were presented for the entire grp Gender: grp. A: % F = 49%; grp. B: % F = 57% Inclusion criteria: patients of 18-60 years of age with LBP in more than 3 months Pain duration of LBP (in months (median (quartiles))): grp.A - 17 (6 to 47); grp.B - 8 (4 to 41) Exclusion criteria: ongoing insurance claim, unsettled social pension claim, LBP caused by major accident, pain extension below knee, excessive distribution of pain according to a pain drawing, neurological diseases including known disc herniation, significant medical diseases including cancer, inflammation, language problems, suspected non-compliance or planned other treatment in the first 4 weeks
Interventions	1) SMT + exercise (N = 35); 2) exercise alone (no SMT) (N = 37) SMT: performed with a specific thrust (high velocity, low amplitude) at the level of reduced movement, called dysfunction (reference to Greenman PE. Principles of Manual Medicine). The type of manipulator not clear nor is the training. Medical manipulator? Exercises (extension): All patients were instructed in 2 simple extension exercises (extension-in-lying, and repeated extension-in-standing). The exercises were to be performed 3 to 5 times with a gradual increase of the extension. After a short break the procedure was to be repeated 4 to 6 times. The patients were instructed to perform these exercises as often as possible during the day and at least once per hour Three office visits were conducted over a period of 4 weeks (baseline, 2 and 4 weeks)
Outcomes	Pain: NRS (0 to 10) for worst pain within the last 48 h for both low-back and leg pain; Back-pain specific functional status: not measured; recovery - not reported; manual medical examination: number of segments with reduced movement; adverse events - 4 pts. in the SMT + exercise grp. reported worsening of the LBP vs. 3 pts. in the no SMT

	+ exercise grp. - no patient was hospitalised due to LBP or disc herniation; (Comment: Outcomes were not defined as primary or secondary by the authors) Follow-up: 2 & 4 weeks, 1 year
Notes	Authors results and conclusions: Pain in both back and legs decreased without differences between the grps. No additional effect was demonstrated of manipulation when extension exercises were used as a basic therapy Funding by the Oak Foundation Uncertain what the background is of the primary and co-authors

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Half of the patients were randomised to a manipulative therapy. The information of whether to receive manipulation or not was given to the examiner in an envelope in the medical chart to be opened by the end of the manual medical examination, when the patient was lying on the side. The patients were not informed of their therapy (manipulation or not) before the end of the follow-up, then a letter with a description of the randomisation was sent to their general practitioner who had referred the patient to the study Unclear if these were sequentially numbered, opaque envelopes
Allocation concealment (selection bias)	Unclear risk	Note: no other information was provided regarding randomisation or allocation
Blinding (performance bias and detection bias) All outcomes - patients	High risk	There is no mention of attempts to blind the patients to other interventions or their perceptions of potential effectiveness of the different interventions
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". Below includes the authors attempt at blinding the "outcomes assessor" "Blinding was attempted by placing the manipulation at the end of an extended examination. Our results did not point towards such bias as the results in the manipulated group were no better than in controls.....The blinding of the examiner was furthermore attempted by mixing patients at differ-

Rasmussen 2008 (*Continued*)

		ent stages of the project" (comment: no statement as to whether the outcome assessor was blinded to treatment allocation)
Incomplete outcome data (attrition bias) All outcomes - drop-outs	High risk	56 patients responded to the questionnaires after three months and one year (= 78%); no data was presented for the 3 months (note: was this pre-planned by the authors?); acceptable drop-out rate for the 1-year data. Unclear why patients dropped-out; this was not described
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Low risk	According to the authors an ITT analysis was performed; however, this represents a complete case-analysis. No attempt was made to correct for missing data
Selective reporting (reporting bias)	High risk	Functional status and recovery - not reported; no published protocol available
Group similarity at baseline	Low risk	Similar for the most important sociodemographic measures, including baseline pain; however, manipulation grp. (A) had much longer pain duration than grp. B (17 months: median, IQR: 6 to 47 vs. 8 months: median, IQR: 4 to 41]
Influence of co-interventions	Unclear risk	Not stated.
Compliance with interventions	Low risk	Regarding exercise: after 4 weeks 100% reported daily exercises, and at one-year follow-up 79% in group A and 75% in group B respectively, reported to be exercising as instructed several times per week. Baseline values or changes in these were not related to compliance at one-year follow-up. Note: according to fig.1 - all patients randomised to the 2 grps. returned at 2 & 4 weeks; therefore, would have received their manipulative treatment, if assigned
Timing of outcome assessments	Low risk	

Rasmussen-Barr 2003

Methods	RCT; unclear allocation procedure
Participants	47 patients randomly allocated to 2 treatment groups; setting: physiotherapy clinic in Stockholm, Sweden; period of recruitment from 1999-2000 Age (median(SD)): ST - grp.: 39 (12); MT - grp.: 37 (10) Gender: ST - grp: 71% F; MT - grp: 78% F

	Inclusion criteria: Men and women aged 18 to 60 years with LBP (pain > 6 weeks) with or without radiation to the knee and pain provoked by provocation tests of lower lumbar segments; with subacute, chronic or recurrent low-back pain Duration LBP (> 3 months): 88% - exercise group; 91% - manual therapy group Exclusion criteria: Prior segmental stabilizing training, manual treatment in the previous 3 months, prior spinal surgery, radiation to the leg or legs with overt neurological signs, pregnancy, known lumbar disc hernia, diagnosed inflammatory joint disease, known severe osteoporosis, or known malignant disease
Interventions	1) Stabilizing training group (N = 24): The ST-group patients underwent a 6-week treatment programme, meeting individually with a physiotherapist (MT) once a week for 45 min. The patients were told how to activate and control their deep abdominal and lumbar multifidus (MF) muscles. The first phase was cognitive and the patients were taught how these muscles act as stabilizers for the lumbar spine. The importance of re-learning motor control of these muscles was underlined. The patients were taught how to activate the deep abdominal muscles together with relaxed breathing in different positions (e.g. supine crooked-lying, four-point kneeling, prone, sitting and standing). The activation of MF together with the deep abdominal muscles was also trained. The physiotherapist monitored the patient by palpating the lower abdominal quadrant for deep tensioning of the abdominal muscles and by palpating the MF at the painful level. A biopressure unit was used in the learning process. The patients were encouraged to perform the exercises daily at home 2) Manual therapy group (N = 23): The MT-group patients underwent a 6-week programme, being treated individually once a week by a physiotherapist (MT) for 45 min. Manual techniques were used, based on findings from the physical examination. They could include a combination of muscle stretching, segmental traction, and soft tissue mobilization and, if needed mobilization of stiff thoracic and upper lumbar segments. No manipulation was done. The patients were encouraged to go on with their usual activities or exercises (not controlled). None of these exercises included specific stabilizing exercises. The patients were also taught basic ergonomics
Outcomes	Pain: VAS (0 to 10 cm); Back-pain specific functional status: Oswestry & Disability Rating Index (a 12-item back-specific questionnaire); recovery - not reported; general health status: VAS (0 to 10 cm); satisfaction: VAS (0 to 10 cm); patients were also queried at 3 & 12 months regarding whether they had sought additional physiotherapy following the last therapy session; adverse events - not reported (comment: Outcomes not defined as primary or secondary by the authors.) Follow-up at 6 weeks (post-treatment), 3 & 12 months
Notes	Authors results and conclusions: Following the tx. period, there was a significant difference between the grps. in assessed function. More individuals in the ST-grp. had improved than the MT-grp. At 3 months, the ST-grp. performed significantly better in terms of pain, functional status, and general health. In the long-term, pts. in the MT-grp. reported more recurrent periods Funding by the Anne-Marie and Ragnar Hemborg Foundation. All authors were registered physiotherapists.
Risk of bias	

Rasmussen-Barr 2003 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The first woman and first man included in the study were randomised to one of the groups by lot (25 ST cards and 25 MT cards in a box). The men and the women were then separately and consistently randomised to either group. At randomisation the patients were assigned a unique code
Allocation concealment (selection bias)	Unclear risk	Unclear to what extent the physiotherapist was involved in the treatment allocation; no mention of an independent research assistant involved in this aspect; thus, unclear what safeguards were in place to protect sequence generation
Blinding (performance bias and detection bias) All outcomes - patients	High risk	There is no mention of attempts to blind the patients to other interventions or their perceptions of potential effectiveness of the different interventions
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". No mention of an attempt to blind the "outcomes assessor"
Incomplete outcome data (attrition bias) All outcomes - drop-outs	High risk	Follow-up post-treatment (% retained): grp.1 - 22/24 (92%); grp.2 - 19/23 (83%) At 3 months: grp. 1 - 17/24 (71%); grp. 2 - 16/23 (70%) At 12 months: grp. 1 - 17/24 (71%); grp. 2 - 14/23 (61%) No reasons were provided from the authors for drop-outs following the initiation of treatment, although they state given the high number of drop-outs, this study should be considered a pilot study
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Unclear risk	Not stated; presumably the data analysed is based upon the case-data available
Selective reporting (reporting bias)	Unclear risk	Recovery was not reported; no published protocol was available
Group similarity at baseline	Low risk	

Rasmussen-Barr 2003 (*Continued*)

Influence of co-interventions	Unclear risk	By design, patients were not allowed the intervention in which they were not randomised; patients were queried at 3 & 12 months regarding whether they had sought additional physiotherapy following the last therapy session; however, the authors do not report whether other interventions were sought during or following the treatment phase
Compliance with interventions	Unclear risk	Patients in the stabilizing training grp. were required to keep a diary for exercises to be completed at home everyday; however, it is not stated whether these diaries were checked and whether they were compliant with the therapy
Timing of outcome assessments	Low risk	

Skillgate 2007

Methods	RCT; adequate allocation procedure
Participants	409 patients (primarily women) randomly allocated to 2 treatment groups; setting: private clinics; recruited by advertising from employees at 2 large public companies (about 40,000, mainly women in the healthcare sector, schools, and in the postal service) in Stockholm, Sweden from March to September 2005 Age (mean (SD) years): grp. 1 - 46(11); grp. 2 - 48(10) Gender (% F): grp. 1 - 74%; grp. 2 - 68% Inclusion criteria: presence of back and neck pain of the kind that brought about marked dysfunction at work or in leisure time, for at least 2 weeks Duration LBP: grp. 1 - 78% > 3mos.; grp. 2 - 72% > 3 mos. Radiation pattern of pain: ? Exclusion criteria: Symptoms too mild as determined by an administrator, pregnancy, specific diagnoses such as acute slipped disc or spinal stenosis, inability to understand Swedish, visits to a naprapath in the preceding 2 mo. or another manual therapist in the preceding month with the exception of massage. An experienced physician further excluded patients based upon the following: too mild symptoms (the physicians' subjective opinion based on the estimated pain and disability in the questionnaires filled in before the examination, and the results of the anamnesis and physical examination), evidence-based advice during the past month, surgery in the painful area, acute prolapsed disc, spondylolisthesis, stenosis, or "red flags" (older than 55 when the pain debut for the first time, recent trauma in the area, constant pain or pain getting worse in the night, cancer in the past or at present, consumption steroids now or recently, drug abuser, HIV, very bad general health, significant weight loss, very bad disability, intensified pain at the smallest movement, obvious structural deformity of the spine, saddle anesthesia/sphincter disturbance, extended muscle weakness, inflammatory or rheumatic diseases, marked morning stiffness, long-lasting severe disability, or peripheral joints affected)
Interventions	1) Naprapathy (N = 206) - delivered by 1 of 8 experienced Naprapaths; A maximum of 6 treatments were given within 6 weeks in the naprapath's own clinic and a combination of naprapathic manual techniques (such as spinal manipulation/mobilization, massage, and

	stretching) was given adapted to the patient's condition. Preventive and rehabilitating advices on physical activity and ergonomics were often given. Each appointment lasted for about 45 minutes 2) Standard care or "evidence-based" care (provided by physician) (N = 203) - Evidence-based care defined as support and advice on staying active and on pain coping strategies including locus of control, according to guidelines, and evidence-based reviews.The evidence-based care was given in direct conjunction with the medical examination (an additional 15 min). The care involved advice and support according to the best scientific evidence available, aiming to empower the patient with an understanding of the importance of staying active and living as normal a life as possible, including work and physical activities. The care also aimed to improve the pain coping strategies. Advice on exercises was general and adapted to the patient's condition. A booklet with examples of exercises and general information on back and neck pain was provided
Outcomes	Primary outcomes (as defined by the authors): pain and disability as measured by a modified version of the Chronic Pain Questionnaire by von Korff, which consisted of each 3 items measuring both pain and disability. Neck pain was measured by the Whiplash Disability Questionnaire. Secondary outcomes: perceived recovery (based upon an 11-point scale) and subsequently dichotomized. adverse events - none were serious; limited to minor short-term reactions such as muscle soreness, tiredness, and increased pain, typically following the first 2 treatments Follow-up at 3, 7 and 12 weeks.
Notes	Authors results and conclusions: At 7 & 12 weeks, statistically significant differences were found between the groups for all outcomes favouring naprapathy; separate analyses for neck and back pain showed similar results. This trial suggests that combined manual therapy, like naprapathy, might be an alternative to consider for back and neck pain patients Funding: Swedish Research Council, the Stockholm County Council, the Uppsala County Council, Capio; the Swedish Naprapathic Association and Health Care Science Post-Graduate School at Karolinska Institute Long-term data (1 year) to be available in a 2010 publication (not published at the time of this review)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Included patients were assigned to 2 groups by randomisation and no pre stratification or blocking was used. An assistant not involved in the project prepared 500 opaque, sequentially numbered sealed envelops with cards numbered 1 or 2 (randomised by a computer), indicating the 2 interventions. Patients were sequentially numbered in the order they came to the study center and received the assignment envelope with the corresponding number

Allocation concealment (selection bias)	Low risk	The unmasking was performed by the physician after the medical examination, so that the assistant, the physician, and the patient were all blind to the group assignment until after all patient baseline data were collected
Blinding (performance bias and detection bias) All outcomes - patients	High risk	There is no mention of attempts to blind the patients to other interventions or their perceptions of potential effectiveness of the different interventions
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". No mention of an attempt to blind the "outcomes assessor". All outcomes in the trial were self-rated by web-based or postal questionnaire 5 times during the year following inclusion
Incomplete outcome data (attrition bias) All outcomes - drop-outs	Low risk	Follow-up (% retained) at 3 weeks: Naprapathy - 95% (196/206); Standard care - 92% (186/203) At 7 weeks: Naprapathy - 94% (194/206); Standard care - 91% (184/203) At 12 weeks: Naprapathy - 95% (195/206); Standard care - 89% (180/203)
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Low risk	
Selective reporting (reporting bias)	Low risk	Protocol published. See http://isrctn.org/ISRCTN56954776
Group similarity at baseline	Low risk	
Influence of co-interventions	Unclear risk	The treatments in both groups were conformed to the patients' condition, but standardized as far as possible concerning, for example, the length of treatment sessions and how to perform them in different situations, by several group meetings held in advance with the physicians and the naprapaths
Compliance with interventions	Unclear risk	Not explicitly stated, but there was high retention in both groups

Skillgate 2007 (*Continued*)

Timing of outcome assessments	Low risk	

UK BEAM trial 2004

Methods	RCT; adequate allocation procedure
Participants	1334 patients were randomly allocated to 6 treatment groups; recruited from 181 general practices (in 14 centres) from the General Practice Research Framework; conducted in the United Kingdom; period of recruitment not reported Age: overall - 43.1 (11.2) years Gender: overall - 56.1 % F Inclusion criteria: Patients were eligible if: Their ages were between 18 and 65 years; were registered for medical care with a participating practice; had consulted with simple low-back pain-pain of musculoskeletal origin in the area bounded by the lowest palpable ribs, the gluteal folds, and the posterior axillary lines, including pain referred into the legs provided it was mainly above the knee; had a score of four or more on the Roland disability questionnaire at randomisation; had experienced pain every day for the 28 days before randomisation or for 21 out of the 28 days before randomisation and 21 out of the 28 days before that; agreed to avoid physical treatments, other than trial treatments, for three months Duration current episode > 3 months: 58.7% for all groups. Exclusion criteria: Patients were not eligible if: They were aged 65 or over, because the spinal manipulation package could be more hazardous in older people with osteoporosis; there was a possibility of serious spinal disorder, including malignancy, osteoporosis, ankylosing spondylitis, cauda equina compression, and infection; complained mainly of pain below the knee, as clinical outcome was likely to be different; had previously had spinal surgery, as clinical outcome was likely to be very different; had another musculoskeletal disorder that was more troublesome than their back pain; had previously attended, or been referred to, a specialised pain management clinic; had a severe psychiatric or psychological disorder; had another medical condition, such as cardiovascular disease, that could interfere with therapy; had moderate to severe hypertension (systolic blood pressure > 180 mm Hg or diastolic blood pressure > 105 mm Hg, on at least two separate occasions; were taking anticoagulant treatment; were taking long term steroids, which might lead to osteoporosis; could not walk 100 m when free of back pain, because exercise would be difficult; could not get up from and down to the floor unaided; had received physical therapy (including acupuncture) in the previous three months; had a Roland disability questionnaire score of three or less on the day of randomisation; could not read and write fluently in English
Interventions	1) Best care in general practice (N = 338); 2) Best care plus exercise alone (N = 310); 3) Best care plus private manipulation alone (N = 180); 4) Best care plus NHS manipulation alone (N = 173); 5) Best care plus private manipulation plus exercise (N = 172); 6) Best care plus NHS manipulation plus exercise (N = 161) Best care in general practice = based upon the UK national acute back pain guidelines, which advise continuing normal activities and avoiding rest. Clinical and support staff from the participating practices were invited to training sessions on the "active management" of back pain. Copies of "The Back Book" were provided as well as the corresponding patient booklet

UK BEAM trial 2004 (*Continued*)

	Exercise programme = developed ("back to fitness") from previous trials. It comprises initial individual assessment followed by group classes incorporating cognitive behavioural principles. We trained physiotherapists with at least two years' experience since qualification to deliver this programme. Classes ran in local community facilities. Up to 10 people took part in each session. We invited participants to attend up to eight 60 minute sessions over four to eight weeks and a "refresher" class 12 weeks after randomisation Manipulation = A multidisciplinary group developed a package of techniques representative of those used by the UK chiropractic, osteopathic, and physiotherapy professions. The three professional associations agreed to the use of this package in this trial. Similar numbers of qualified manipulators from each of these professions treated participants. They all had a minimum of two years' clinical experience and were skilled in a range of manipulative techniques, including high velocity thrusts. Participants randomised to private manipulation received treatment in manipulators' own consultation rooms. Those randomised to NHS manipulation saw the same manipulators in NHS premises. Following initial assessment, manipulators chose from the agreed manual and non-manual treatment options. They agreed to do high velocity thrusts on most patients at least once.We invited participants to attend up to eight 20 minute sessions, if necessary, over 12 weeks Combined treatment = We invited participants to attend eight sessions of manipulation over six weeks, eight sessions of exercise in the next six weeks, and a refresher class at 12 weeks. Other aspects of treatment were identical to those in the manipulation only or exercise only groups
Outcomes	"Main outcome measures" (as defined by the authors) - Pain: not reported separately; Back-pain specific functional status: Roland-Morris (RMDQ) & Modified von Korff scale (composite scale of pain and disability); Recovery - not reported; Beliefs: Back Beliefs Questionnaire (BBQ) & Fear-Avoidance Beliefs Questionnaire (FABQ); General health: SF-36 & EuroQol; Specific health transition (Beurskens et al.); Troublesomeness (Deyo et al.); Distress and Risk Assessment Method (DRAM); adverse events (serious adverse events - defined as an event leading to hospitalisation or death within one week of treatment) - no serious adverse events were reported. Comment: There were no defined secondary outcomes Cost-effectiveness data available, published under a separate document at: http://www.bmj.com/content/329/7479/1381 Follow-up at 3 & 12 months
Notes	Authors results and conclusions: All groups improved with time. Relative to "best care" in general practice, manipulation followed by exercise achieved a moderate benefit at three months and a small benefit at 12 months; spinal manipulation achieved a small to moderate benefit at three months and a small benefit at 12 months; and exercise achieved a small benefit at three months, but not 12 months Funding by Medical Research Council; National Health Service in England, Northern Ireland, Scotland and Wales Note: The differences in change scores for exercise and manipulation, either in combination with one another or alone, were not clinically relevant compared to "best care" for the principal outcome measure, functional status; however, an economic evaluation with this data set suggests (according to the authors) that spinal manipulation is a cost effective addition to "best care" for back pain in general practice. Manipulation alone probably gives better value for money than manipulation followed by exercise

UK BEAM trial 2004 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	After consenting participants had completed baseline assessments, nurses contacted the remote randomisation service by telephone in order to obtain the participants random treatment allocation
Allocation concealment (selection bias)	Low risk	Participants were stratified by practice and allocated between the six treatment groups by randomly permuted blocks
Blinding (performance bias and detection bias) All outcomes - patients	High risk	"As UK BEAM was a pragmatic trial to estimate the effectiveness of manipulation and exercise in routine clinical practice, blinding of participants and professionals was neither desirable nor possible."
Blinding (performance bias and detection bias) All outcomes - providers	High risk	"As UK BEAM was a pragmatic trial to estimate the effectiveness of manipulation and exercise in routine clinical practice, blinding of participants and professionals was neither desirable nor possible."
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". Outcomes were measured via self-report questionnaires
Incomplete outcome data (attrition bias) All outcomes - drop-outs	High risk	Follow-up at 3 months (% retained): GP care - 76%; exercise only - 73%; SMT groups only - 81% & 82%; SMT + exercise groups - 75% & 81% At 12 months: GP care - 73%; exercise only - 69%; SMT groups only - 78% & 77%; SMT + exercise groups - 77% & 78% Note: No explanation was provided as to the reason for the drop-outs
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Low risk	No attempt was made to correct for missing cases through for example, imputation
Selective reporting (reporting bias)	Low risk	Protocol was published separately prior to publication of the study and was available online http://www.controlled-trials.com/ISRCTN32683578/32683578; although recovery not examined as an outcome measure and pain not reported separately

Group similarity at baseline	Low risk	
Influence of co-interventions	Unclear risk	stated in the inclusion criteria; however, unclear whether this was actually checked
Compliance with interventions	Unclear risk	A maximum number of sessions were determined for both the exercise and manipulation group, but it is unclear how many sessions were attended
Timing of outcome assessments	Low risk	

Waagen 1986

Methods	RCT; unclear allocation procedure
Participants	29 subjects randomly allocated to 2 treatment groups; setting: chiropractic college clinic in Iowa, USA; recruitment over a "two-month period" Age (years) (mean (SD not provided)): grp. 1 - 25.2; grp. 2 - 24.3 Gender (% F): grp. 1 - 46% (5/11); grp. 2 - 61% (11/18) Inclusion criteria: 18 to 65 years of age; chief complaint of LBP; patient was naive to chiropractic tx. (note: presumably refers to a new patient who had never undergone chiropractic care). Radiation pattern of pain: no radiation below knee Duration of the current LBP: overall: 2.5 to 2.8 years Exclusion criteria: Pregnancy, malingering, patient who is not ambulatory or receiving Worker's Compensation for a back problem; obesity, radiographic evidence of osseous fractures, osteoporosis, or spondylolisthesis; LBP due to visceral (e.g. kidney, liver, urinary bladder) disorder; disc herniation, severe concurrent infectious or other systemic disease process; neurologic deficits indicated by leg pain, numbness or weakness
Interventions	1) Manipulation (N = 11): treated exclusively with spinal adjustive therapy; no adjunctive or concurrent therapy, either chiropractic or medical, was given during the trial period; therapy consisted of full-spine adjustments in order to correct all chiropractic lesions (i.e. subluxations); the location of the adjustments were determined by palpation, inspection and consultation with the patient 2) Sham manipulation (N = 18): consisted of an adjustment using minimal force for a generalized manipulation; the lumbar drop-piece on a standard chiropractic adjusting table was set to minimal tension; an adjustment was simulated by applying gentle pressure over both posterior superior iliac spines such that the lumbar section fell; soft-tissue massage was also provided All patients were treated 2 to 3 times weekly for 2 weeks (total 4 to 6 txs) by experienced chiropractors from the college faculty
Outcomes	Pain: 10-cm. VAS; Back-pain specific functional status and recovery: not reported; spinal mobility (consisting of active and passive SLR to both sides, lumbar flexion, extension and lateral bending - in total 8 measures and a "global index" is presented which gives an overall change for these measures); recovery - not reported; adverse events - not reported; comment: Outcome measures were not defined as primary or secondary by the authors

Waagen 1986 (*Continued*)

	Follow-up: 2 weeks
Notes	Authors results and conclusions: Experimental patients had significantly more relief from pain as well as global change in spinal mobility than the controls. Given the small sample size, the results reported must be considered preliminary Funded by Palmer College of Chiropractic. Unclear what the background of the authors is.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Patients were randomly assigned to one of the two tx. grps. using a code based upon the patient number issued when the patient was first admitted to the clinic
Allocation concealment (selection bias)	Unclear risk	Note: no other information was provided on the sequence generation or allocation
Blinding (performance bias and detection bias) All outcomes - patients	Low risk	Patients assigned to either a real or sham treatment. The success of blinding was assessed during a post-trial interview. Eleven (6 sham SMT-grp., 5 SMT grp.) of the 15 pts. thought they had received "standard" (or real) chiropractic adjustments, while 4 patients (3 sham SMT grp., 1 SMT grp.) thought they had received the sham treatment
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	Low risk	Assessment of treatment effects was conducted by a grp. of licensed chiropractors who were not involved in treating the patients. Evaluating clinicians were blinded with regard to the type of treatment received by the patients. Post-treatment evaluation of the patients suggests that blinding was successful
Incomplete outcome data (attrition bias) All outcomes - drop-outs	High risk	At 2 weeks (% retained): grp.1 - 82% (9/11); grp. 2 - 56% (10/18) Overall at 2 weeks: 66% (19/29)
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Unclear risk	Not stated, but small study with large and differential degree of drop-out

Waagen 1986 (*Continued*)

Selective reporting (reporting bias)	High risk	No published protocol available; back pain specific function and recovery not reported
Group similarity at baseline	Low risk	Age, duration of the symptoms and function of the lumbar spine (using a untested "global index") were similar, although pre-treatment pain level 1-point difference (11-point scale) between the grps. - no measure of variation is presented; reasonable difference in % females in the 2 grps. (61% vs. 46%)
Influence of co-interventions	Unclear risk	Not stated.
Compliance with interventions	Unclear risk	Not stated.
Timing of outcome assessments	Low risk	

Wilkey 2008

Methods	RCT; adequate allocation procedure.
Participants	30 patients randomly allocated to 2 treatment groups; setting: National Health Services hospital outpatient clinic or chiropractic clinic in the United Kingdom; recruitment period not reported Age (years): grp.1 - 39.8 (range: 26 to 64); grp.2 - 48.5 (range: 31 to 61) Gender (% F): grp.1 - 64%; grp.2 - 50% Inclusion criteria: LBP > 12 weeks with or without radiation into the legs; 18 to 65 years Duration with LBP (mean (range) in years): grp.1 - 4.0 (0.5 to 10); grp.2 - 7.3 (0.5 to 20) Pattern of pain radiation: with or without radiation into the legs Exclusion criteria: neurologic disease ; neurological deficit due to prolapsed HNP; spinal stenosis; acute fracture; h/o spinal surgery; h/o carcinoma; gross anatomical abnormality or high comorbidity due to other diseases
Interventions	1) Hospital pain clinic (N = 12): consisted of standard pharmaceutical therapy (NSAIDs, analgesics, gabapentin), facet joint and soft-tissue injections, and/or TENS. These modalities could be used in isolation or in combination with any of the other modalities 2) Chiropractic treatment (N = 18): All techniques that were employed are recognized within the chiropractic profession as methods used for the treatment of LBP, e.g. side-posture diversified manipulation to the lumbar spine and pelvis; flexion-distraction; trigger point therapy using a large variety of techniques; soft-tissue massage; home exercises were prescribed and advice was given regarding posture and activities of daily living Treatment period was 8 weeks with a maximum of 16 treatment sessions. Both control and treatment groups underwent their therapy within the hospital
Outcomes	Pain: 11-point NRS; Back-pain specific functional status: Roland-Morris; recovery - not reported; adverse events - not reported; Comment: Outcomes were not defined as primary or secondary by the authors

	Follow-up: 2, 4, 6 and 8 weeks
Notes	Authors results and conclusions: At 8 weeks, the mean improvement in RMDQ was 5. 5 points greater for the chiropractic group (decrease in disability by 5.9) than for the pain-clinic group (0.36). Reduction in mean pain intensity at week 8 was 1.8 points greater for the chiropractic group than for the pain-clinic group. This study suggests that chiropractic management administered in an NHS setting may be effective for reducing levels of disability and perceived pain during the period of treatment for a subpopulation with chronic LBP Funded by National Health Services. A pragmatic study (i.e. examined "chiropractic management" rather than SMT alone); data is poorly reported - the figures do not present any measure of variation. Data was requested from the authors for pain and functional status and was received

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Patients were randomised into the treatment or control group by way of sealed envelope (20 envelopes for each group): This consisted of randomly mixed, sealed envelopes being chosen and opened by one of the hospital secretaries who then contacted the patient, advising them of their allocation
Allocation concealment (selection bias)	Low risk	The process of allocation was performed independently of the treating clinicians
Blinding (performance bias and detection bias) All outcomes - patients	High risk	There is no mention of attempts to blind the patients to other interventions or their perceptions of potential effectiveness of the different interventions
Blinding (performance bias and detection bias) All outcomes - providers	High risk	No mention if there were any attempts to blind the care providers to the other groups
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". No mention of trying to blind an "outcomes assessor". Outcomes were assessed by self-report measures, presumably at the facilities where the patients were treated (comment - but this is not clear)
Incomplete outcome data (attrition bias) All outcomes - drop-outs	Low risk	Only 1 in the pain clinic grp. and 2 in the chiropractic tx. grp. did not complete the trial

Wilkey 2008 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes - ITT analysis	Unclear risk	Not stated; however, small trial and only 3 subjects did not complete the trial. Presumably all data was included in the analyses?
Selective reporting (reporting bias)	Unclear risk	No published protocol; recovery not reported.
Group similarity at baseline	Low risk	The mean duration of symptoms within the chiropractic group, 7.34 years (0.5 to 20 years), was almost twice that of those assigned to the pain clinic, 4.04 years (0.5 to 10 years). The peak duration was similar: 3 years for the pain clinic group and 2.5 years for the chiropractic groups, respectively. The mean age for those within the chiropractic group was higher than that of the pain clinic: 48.5 (range 31 to 61) years compared to 39 (range 26 to 64) years. Scores for the principal outcome measures (pain and functional status) were similar at baseline
Influence of co-interventions	Unclear risk	Not stated.
Compliance with interventions	High risk	The mean attendance for treatment in the pain clinic group was 1.9 sessions compared with 11.3 for the chiropractic group. Three patients within the control group were seen only once with treatment administered at the initial consultation with the follow-up falling outside of the 8-week treatment period and only 2 patients within the same group were seen on three occasions over the 8 weeks
Timing of outcome assessments	Low risk	

Zaproudina 2009

Methods	RCT; adequate allocation procedure; randomisation 1:1
Participants	131 patients randomly allocated to 2 treatment groups; setting: private clinics?; conducted in Finland; recruitment via newspaper advertisement from April 2003 to December 2005 Age (years): grp.1 - 40.7 (5.3); grp.2 - 41.7 (5.8) Gender (% F): grp.1 - 53%; grp.2 - 49% Inclusion criteria: chronic LBP, with or without referred leg pain, and with a minimal VAS of 30 (0 to 100) and/or an ODI of at least 16%. From Ritvanen 2007, the following is also to be found: between 20 and 60 years old, had LBP that restricted functioning (referred pain not distal to the knee), and had LBP present on at least half of the days in a 12-month period in a single episode or in multiple episodes Duration LBP: The average duration of LBP was 10.6 years (personal communication

Zaproudina 2009 (*Continued*)

	with primary author) Exclusion criteria: specific pathology (e.g. infection, tumour, osteoporosis, fracture, structural deformity, inflammatory disorder (e.g. ankylosing spondylitis), radicular syndrome or cauda equina syndrome) (personal communication)
Interventions	1) Traditional bone setting (TBS) (N = 65): is based on manual whole body treatment. A bone setter begins the treatment from the toes and feet up to the hands and head and mobilizes tissues and malocclusions. The aims of TBS treatment are usually to abolish malpositions, to relax the muscles, and to remove excessive muscle contraction and body asymmetry. The patients received 5 TBS treatments with 2-week intervals; these were carried out by experienced bone setters 2) Physical therapy (PT) (N = 66): included massage, therapeutic stretching, trunk stabilization exercise, and exercise therapy. The patients treated by PT received an average of 5 treatments (usually weekly - personal communication) and also got instructions for home training; PT was performed by a fitness center specialist The timetable for tx. was chosen by the treatment provider in agreement with the patient
Outcomes	Pain (100-mm visual analogue scale); Back-pain specific functional status (Oswestry); perceived recovery (11-point scale); Health-Related Quality of Life (15D); depression (Rimon's Brief Depression Questionnaire); spinal mobility (finger-floor distance, side-bending, passive straight leg raise); adverse events - not reported. Comment: Outcomes were not defined as primary or secondary by the authors. Note: the earlier publication focused on EMG activity of the paraspinal muscles at L1-2 and L4-5 levels, and the SD's presented for pain and functional status in Ritvanen (T.2) are probably SE's (compared with this publication) Follow-up at 1, 6 & 12 months post-tx., which corresponds approximately to 3, 9, 15 months post-baseline
Notes	Authors results and conclusions: Pain levels as well as spinal mobility did not differ between the groups; however, functional status, perceived recovery and QoL scores tended to favour the TBS grp. Long-term results did not differ between the grps Funded by Finland's Slot Machine Association and in collaboration with the Folk Healing Association This publication is the long-term follow-up to the study by Ritvanen 2007, although short-term outcomes are also reported in this publication. The first part of the study was conducted in 2003 and continued in 2005 with an additional 60 LBP patients. The extension was performed with the same protocol; Health-related quality of life-measurements were, however, added in 2005, while the focus of the earlier publication was on electromyographic (EMG) responses to treatment The primary author was contacted regarding missing information and the following is her response. Low-back pain was defined by European guidelines for the management of chronic non-specific low-back pain as pain and discomfort, localised below the costal margin and above the inferior gluteal folds, with or without referred leg pain, persisting for at least 12 weeks; chronic "non-specific" i.e. low-back pain that is not attributable to a recognisable, known specific pathology (e.g. infection, tumour, osteoporosis, fracture, structural deformity, inflammatory disorder (e.g. ankylosing spondylitis), radicular syndrome or cauda equina syndrome)
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Patients were randomised by a closed envelope system. The closed envelopes were set in two boxes (for men and women separately). Upon leaving, the patients drew an envelope at random. Each envelope contained instructions concerning the examination and treatments and as to which group a patient was randomised
Allocation concealment (selection bias)	Low risk	An independent assessor generated the allocation sequence, enrolled the patients, and assigned the patients to their groups. Comment: based upon information provided in Ritvanen 2007
Blinding (performance bias and detection bias) All outcomes - patients	High risk	"The researchers were blinded in the selection intervention group, but the treatment providers and subjects were not blinded."
Blinding (performance bias and detection bias) All outcomes - providers	High risk	"..... the treatment providers and subjects were not blinded."
Blinding (performance bias and detection bias) All outcomes- outcome assessors	High risk	Patient was not blinded; therefore, this item was scored as "no". No mention of trying to blind an "outcomes assessor". Self-reported outcome measures
Incomplete outcome data (attrition bias) All outcomes - drop-outs	Low risk	Follow-up at 1 month post-treatment (% retained): grp.1 - 88% (57/65); grp.2 - 91% (60/66) At 12 months post-treatment: grp.1 - 77% (50/65); grp.2 - 80% (53/66)
Incomplete outcome data (attrition bias) All outcomes - ITT analysis	High risk	Some subjects were quite clearly excluded from the analyses for various reasons in both groups: operated on the back (N = 3) or discontinued because of worsening (N = 3), thus representing a "per-protocol" analysis
Selective reporting (reporting bias)	Low risk	Published protocol (ISRCTN 13338472; http://www.controlled-trials.com/ISRCTN13338472) and all 3 primary outcomes were reported.

Group similarity at baseline	Low risk	
Influence of co-interventions	Unclear risk	Not stated.
Compliance with interventions	Unclear risk	Not stated.
Timing of outcome assessments	High risk	Pre-post treatment analysis. First post-tx. analysis was performed one month after the last tx. session. Pt's informed the researchers when tx. was completed and the first post-tx. was planned one month from the last session. In FT grp., all patients received 5 tx. sessions and in TBS grp. sessions ranged on avg. from 3 to 5 (personal communication) TBS grp. received 5 txs at 2 week intervals; therefore, post-tx = ~10 weeks; FT grp. received 5 txs. usually weekly; therefore, post-tx. = ~at 5 weeks. Thus, difference in timing would be approximately one month, which could be important for the short-term follow-up

BMI = body-mass index; EMG = electromyograph; FABQ = Fear Avoidance Beliefs Questionnaire; FT or PT = physiotherapist or physical therapist; GP = general practitioner; GPE = global perceived effect; grp. = group; h/o = history of; HVLA = high-velocity low-amplitude; IQR = interquartile range; ITT = intention to treat analysis; no. txs = number of treatments; NRS = numerical rating scale; ODI = Oswestry Disability Index; OMT = osteopathic (or orthomanual) manipulative therapy; post-tx. = post-treatment; pt. = patient; RCT = randomised controlled trial; ROM = range of motion; SD = standard deviation; SIP = Sickness Impact Proflle; SI joint = sacroiliac joint; SLR = straight leg-raise; SMT = spinal manipulative therapy; tx. = treatment; VAS = visual analogue scale; wks. = weeks; yr. = year.

Number of subjects listed following the definition of the intervention is the number of subjects allocated to the intervention and not necessarily the number that actually received the intervention or were available for assessment.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Andersson 1999	Proportion with chronic low-back pain longer than 12 weeks unclear
Arkuszewski 1986	Only alternate, no truly randomised allocation
Aure 2003	Contribution of SMT to the treatment effect could not be discerned. The aim of this study was to compare the effect of manual therapy, including specific exercises and segmental techniques to general exercise therapy in chronic LBP patients

(*Continued*)

	The trial was also identified in the literature search conducted for the European Guidelines for the Management of Chronic Low-back pain (European Spine Journal 2006; 15(supplement 2): see p. S241; also available from http://www.backpaineurope.org/web/files/WG2_Guidelines.pdf). However, they excluded it because "the patients in the manual therapy group also received a substantial amount of exercise therapy, making the respective effects of the manual therapy and the exercise therapy difficult to ascertain". This study was also excluded from the section on exercises for the same reason
Beyerman 2006	Duration of low-back pain unspecified
Brennan 1994	No relevant outcome measure (pain or disability)
Brønfort 1989	Mean duration low-back pain less than 12 weeks
Brønfort 2004	Evaluates exclusively sciatica; included low-back pain patients with radiating pain into the proximal or distal part of the lower extremity, with or without neurologic signs
Burton 2000	Evaluates exclusively sciatica (leg pain worse than back pain); unilateral, unremitting pain; positive straight leg raising test with positive nerve root tension signs, radiculopathy limited to a single nerve root. In addition, there was unequivocal evidence of single-level non-sequestrated lumbar disc herniation on either computed tomography (CT) or magnetic resonance imaging (MRI)
Cherkin 1998	Mean duration low-back pain less than 12 weeks
Cote 1994	No patients; assessment < 1 day; no relevant outcome measure (pain or disability)
Coxhead 1981	Evaluates exclusively sciatica (with or without back pain).
Coyer 1955	Only alternate, not truly randomised
Doran 1975	Proportion with low-back pain longer than 12 weeks unclear
Ellestad 1988	Not all subjects LBP; no relevant outcome measure
Geisser 2005	Not SMT as defined in this review - "muscle energy technique" which did not involve manipulation or mobilization of the spine
Gibson 1993	No patients (healthy subjects); no relevant outcome measure; follow-up < 1 day
Gilbert 1985	No manual mobilization / manipulation
Glover 1974	Duration low-back pain unspecified
Haas 1995	No patients; no relevant outcome measure; follow-up < 1 day
Haas 2004	RCT of SMT which evaluated the effects of the number of chiropractic treatment visits for SMT only *versus* SMT + physical modalities for chronic low-back pain and disability; all subjects received high-velocity low-amplitude SMT

(*Continued*)

Hawk 2006	Did not specifically examine chronic LBP in the analysis of the data
Helliwell 1987	No relevant outcome measure
Herzog 1991	Proportion with low-back pain longer than 12 weeks unclear
Hoehler 1981	Mean duration low-back pain less than 12 weeks
Hough 2007	Quasi-RCT; participants were alternately included
Hsieh 1992	Proportion with low-back pain longer than 12 weeks unclear
Indahl 1995	No manipulation / mobilization
Khalil 1992	Stretching, no real manipulation
Kinalski 1989	Duration low-back pain unspecified
Kokjohn 1992	No low-back pain patients; follow-up < 1 day
Lewis 2005	Contribution of SMT to the treatment effect could not be discerned
MacDonald 1990	Proportion with low-back pain longer than 12 weeks unclear
Marshall 2008	Not an RCT involving SMT; participants were randomised to 2 forms of exercise (and not SMT)
Mathews 1987	Mean duration low-back pain less than 12 weeks
Meade 1990/1995	Proportion with low-back pain longer than 12 weeks unclear
Niemisto 2003/2005	Contribution of SMT to the treatment effect could not be discerned
Nwuga 1982	Alternate, no truly random allocation
Ongley 1987	Contribution of SMT to the treatment effect could not be discerned; participants in the SMT treatment-arm received only one manipulation treatment, in addition to other treatment modalities
Petty 1995	No random allocation
Rupert 1985	Proportion with low-back pain longer than 12 weeks unclear
Shearar 2005	Proportion with low-back pain longer than 12 weeks unclear
Siehl 1971	No relevant outcome measure
Sims-Williams 1978	Duration of low-back pain unspecified

(*Continued*)

Skagren 1997	Mean duration with low-back pain less than 12 weeks
Terrett 1984	No relevant outcome measure
Timm 1994	Post-surgical evaluation of SMT
Triano 1995	Proportion with low-back pain longer than 12 weeks unclear; included subjects >50 days of LBP
Wreje 1992	Majority with low-back pain less than 12 weeks
Zylbergold 1981	Duration of low-back pain unspecified

Characteristics of studies awaiting assessment *[ordered by study ID]*

Cleland 2006

Methods	Official title: Comparison of the Effectiveness of Three Manual Physical Therapy Techniques in a Subgroup of Patients With Low-Back Pain Who Satisfy a Clinical Prediction Rule: A Randomised Clinical Trial Purpose: The purpose of this study is to investigate the effectiveness of three different manual therapy techniques in a subgroup of patient with low-back pain that satisfy the clinical prediction rule
Participants	Inclusion Criteria: 1. Chief complaint of pain and/or numbness in the lumbar spine, buttock, and/or lower extremity 2. Oswestry disability score of at least 25% 3. Age greater than 18 years and less than 60 years 4. At least four out of five of the following criteria:Duration of current episode < 16 days (judged from the patient's self-report)No symptoms extending distal to the knee (judged from the pain diagram) FABQ-W score < 19. At least one hip with > 35° internal rotation range of motion (measured in prone). Stiffness in the lumbar spine (judged from segmental mobility testing) Exclusion Criteria: 1. Red flags noted in the participant's general medical screening questionnaire (i.e. tumour, metabolic diseases, RA, osteoporosis, prolonged history of steroid use, etc.) 2. Signs consistent with nerve root compression, this includes any one of the following:Reproduction of low-back or leg pain with straight leg raise at less than 45°; Muscle weakness involving a major muscle group of the lower extremity; Diminished lower extremity muscle stretch reflex (Quadriceps or Achilles tendon); Diminished or absent sensation to pinprick in any lower extremity dermatome 3. Prior surgery to the lumbar spine or buttock 4. Current pregnancy 5. Past medical history of osteoporosis or spinal compression fracture 6. Inability to comply with treatment schedule (weekly sessions for four weeks)
Interventions	Mobilization
Outcomes	

Notes	Study completed. Principal investigator: Joshua Cleland, DPT, OCS. Sponsor: Franklin Pierce University. Collaborator: University of Southern California. link:http://clinicaltrials.gov/show/NCT00257998. To determine if the population has a mean duration > 12 weeks with low-back pain

Characteristics of ongoing studies *[ordered by year of study]*

NCT00410397

Trial name or title	The use of manual therapy to treat low-back and hip pain
Methods	RCT Target sample size: 27
Participants	Inclusion Criteria: Written informed consent; 18 to 65 years of age; lumbopelvic pain; no limits on duration? Exclusion Criteria: Cardiovascular disease (heart-failure, myocardial infarction, hypertension), diabetes, rheumatoid arthritis, osteoarthritis, chronic illness, pregnancy, neurodegenerative disease, osteopenia, osteoporosis, cancer
Interventions	osteopathic manipulation. Study focuses on treating pelvic muscle pain as a way of lessening LBP
Outcomes	Primary Outcome Measures: Reduction in low-back pain on a 1 to 10 scale. (Time Frame: Immediately following treatment.) Secondary Outcome Measures: Reduction in low-back pain on a 0 to 10 scale. (Time Frame: 6 to 8 hours after treatment.) Reduction in low-back pain on a 0 to 10 scale. (Time Frame: After four weeks of therapy.)
Starting date	December 2006
Contact information	Principal Investigator: Correy R Babb, Oklahoma State University of Osteopathic Medicine
Notes	http://clinicaltrials.gov/show/NCT00410397 Oklahoma State University Center for Health Sciences

NCT00567333

Trial name or title	Individualized chiropractic and integrative care for low-back pain
Methods	RCT The primary aim of this study is to determine the relative clinical efficacy of 1) chiropractic care and 2) multidisciplinary, integrative care in 200 patients with sub-acute or chronic LBP, in both the short-term (after 12 weeks) and long-term (after 52 weeks) Chiropractic care will include therapies within the professional scope of practice. Integrative, multidisciplinary care will include chiropractic, massage therapy, traditional Chinese medicine (including acupuncture) , medication, cognitive behavioral therapy, exercise, and patient education Secondary aims are to assess between group differences in frequency of symptoms, disability, fear avoidance behavior, self efficacy, general health, improvement, patient satisfaction, work loss, medication use, lumbar

NCT00567333 (*Continued*)

	dynamic motion, and torso muscle endurance. Patients' and providers' perceptions of treatment will be described using qualitative methods and cost-effectiveness and cost utility will be assessed in the short- and long-term
Participants	Inclusion Criteria: Mechanical LBP classified as 1, 2, 3, or 4 using Quebec Task Force (QTF) classification. (This includes back pain, stiffness or tenderness with or without musculoskeletal and neurological signs); LBP localized to posterior aspect of body, below the costal margin and above the inferior gluteal folds; pain level > 3 on 0 to 10 scale; current LBP episode > 6 weeks duration; 18 years of age and older; stable prescription medication plan (No changes in prescription medications that affect musculoskeletal pain in the previous month.) Exclusion Criteria: Ongoing treatment for LBP by other non-study providers; Progressive neurological deficits or cauda equina syndrome; QTF classifications 5 (spinal instability or fracture) and 11 (other diagnoses including visceral diseases, compression fractures, metastases). These are serious conditions not amenable to the conservative treatments proposed: QTF 7 (Spinal stenosis syndrome characterized by pain and/or paraesthesias in one or both legs aggravated by walking); uncontrolled hypertension or metabolic disease; blood clotting disorders; severe osteoporosis; inflammatory or destructive tissue changes of the spine; patients with surgical lumbar spine fusion or patients with multiple incidents of lumbar surgery; pregnant or nursing women
Interventions	Chiropractic care (A combination of professional therapies with the scope of practice, including spinal manipulation therapy, spinal mobilization, stretching and strengthening exercises, and self-care education). Multidisciplinary, integrative care (A combination of therapies which may include acupuncture/Oriental medicine, chiropractic, cognitive behavioral therapy, exercise therapy, medicine, self-care information, and massage therapy)
Outcomes	Primary Outcome Measures: Patient-rated back pain. (Time Frame: Short term: 12 weeks, Long term: 52 weeks) (Designated as safety issue: No) Secondary Outcome Measures: Frequency of Symptoms (Time Frame: 12 and 52 weeks) (Designated as safety issue: No) Low-Back Disability (Time Frame:12 and 52 weeks) (Designated as safety issue: No) Fear Avoidance (Time Frame:12 and 52 weeks) (Designated as safety issue: No) Self-Efficacy (Time Frame: 12 and 52 weeks) (Designated as safety issue: No) General Health Status (Time Frame:12 and 52 weeks) (Designated as safety issue: No) Improvement (Time Frame:12 and 52 weeks) (Designated as safety issue: No) Patient Satisfaction (Time Frame:12 and 52 weeks) (Designated as safety issue: No) Work Loss (Time Frame:12 and 52 weeks) (Designated as safety issue: No) Medication Use (Time Frame:12 and 52 weeks) (Designated as safety issue: No) Objective biomechanical measurements: Lumbar Dynamic Motion and Torso Muscle Endurance. (Time Frame: Short term:12 weeks) (Designated as safety issue: No)
Starting date	June 2007; recruitment completed, currently in the follow-up phase. Estimated completion: October 2010
Contact information	Principal investigator: Gert Brønfort, DC, PhD
Notes	http://clinicaltrials.gov/show/NCT00567333 Primary sponsor: Northwestern Health Sciences University

NCT00632060

Trial name or title	The efficacy of manual and manipulative therapy for low-back pain in military active duty personnel: A feasibility study
Methods	RCT Target sample size: 100
Participants	Inclusion Criteria: Active Duty; aged 18 to 35; new episode of low-back pain (LBP) or a recurrence of a past episode of low-back pain; no limitations on duration of the presenting LBP Exclusion Criteria: LBP from other somatic tissues as determined by history, examination, and course (i. e. pain referred from visceral conditions); radicular pain worse than back pain; co-morbid pathology or poor health conditions that may directly impact spinal pain. Patients who have case histories and physical examination findings indicating other than average health will be excluded from the study; bone and joint pathology contraindicating patient for M/MT. Patients with spinal fracture, tumours, infections, inflammatory arthropathies and significant osteoporosis will be referred for appropriate care and will be excluded from the study; other contraindications for M/MT of the lumbar spine and pelvis (i.e. bleeding disorders or anticoagulant therapy); pregnancy (all potential female participants will undergo pregnancy testing); use of manipulative care for any reason within the past month; unable to follow course of care for four weeks; unable to give informed consent for any reason; unable to confirm that they will not be deployed during the course of the study: "Will you be deployed, receiving orders for a distant temporary active duty assignment, attending training at a distant sight, or otherwise absent from Ft. Bliss over the next 6 weeks?"
Interventions	1) No Intervention Standard Care Control Group - Participants randomised to the standard care group will continue their use of non-prescription or prescription medication and reduced duty loads, as prescribed by the credentialed medical provider 2) Experimental Manual / Manipulative Therapy Group: Participants randomised to the M/MT group will receive a course of M/MT along with standard care. The patient will see the chiropractor twice a week for the entire course of the study, regardless of manipulation or not
Outcomes	Primary Outcome Measures: Decreased pain (Time Frame: Baseline, 2 & 4 weeks) Secondary Outcome Measures: Increased function (Time Frame: Baseline, 2 & 4 weeks)
Starting date	February 2008
Contact information	Roxana Delgado, MS; Keith P Meyers, MD
Notes	http://clinicaltrials.gov/show/NCT00632060 Primary sponsor: Samueli Institute for Information Biology. Collaborators: Palmer Center for Chiropractic Research (PCCR); William Beaumont Army Medical Center; United States Army Fort Bliss

NCT00315120

Trial name or title	A randomised controlled trial of osteopathic manipulative treatment and ultrasound physical therapy for chronic low-back pain
Methods	RCT Target sample size: 488

NCT00315120 (*Continued*)

Participants	21-69 years of age with chronic LBP Inclusion Criteria: Must give a positive response to the question: "Have you had low-back pain constantly or on most days for the last three months?"; Must identify the low back as the primary site of pain; Must agree to not receive any of the following outside of the study during the period of participation: osteopathic manipulative treatment, chiropractic adjustment (including "mobilization" or "manipulation"), physical therapy; Women must not be pregnant or plan to become pregnant during the period of study participation (a negative pregnancy test and willingness to maintain an acceptable method of contraception will be required) Exclusion Criteria: History of any of the following conditions which may be underlying causes of low-back symptoms: cancer, spinal osteomyelitis, spinal fracture, herniated disc, ankylosing spondylitis, cauda equina syndrome; History of surgery involving the low back within the past year or planned low-back surgery in the future; History of receiving Workers' Compensation benefits within the past three months; Involvement in current litigation relating to back problems; Current pregnancy or plan to become pregnant during the course of participation in the study; Any of the following that may limit a provider's choice of osteopathic manipulative treatment techniques or hamper compliance with the study protocol: angina or congestive heart failure symptoms that occur at rest or with minimal activity, history of a stroke or transient ischemic attack within the past year; Any of the following that may represent potential contraindications to receiving ultrasound physical therapy: implantation of a cardiac pacemaker, implantation of artificial joints or other biomedical devices, active bleeding or infection in the low back, pregnancy; Use of intravenous, intramuscular, or oral corticosteroids within the past month; History of osteopathic manipulative treatment, chiropractic adjustment, or physical therapy within the past three months or on more than three occasions during the past year; Practitioner or student of any of the following: osteopathic medicine (D.O.) allopathic medicine (M. D.), chiropractic (D.C.), physical therapy
Interventions	1) Active osteopathic manipulation and active ultrasound physical therapy 2) Sham osteopathic manipulation and active ultrasound physical therapy 3) Active osteopathic manipulation and sham ultrasound physical therapy 4) Sham osteopathic manipulation and sham ultrasound physical therapy
Outcomes	Primary Outcome Measures: Visual analogue scale score for pain (Time Frame: 1, 2, 4, 8 & 12 weeks) Secondary Outcome Measures: Roland Morris Disability Questionnaire; Medical Outcomes Study SF-36 Health Survey; Work disability; Satisfaction with back care (Time Frame: 4, 8 & 12 weeks)
Starting date	August 2006; estimated study completion date: June 2010
Contact information	Principal investigator: John Licciardone, DO, MS, MBA
Notes	http://clinicaltrials.gov/show/NCT00315120 Principal sponsor: University of Horth Texas Health Science Center

ISRCTN47636118

Trial name or title	Efficacy of conventional physiotherapy and manipulative physiotherapy in the treatment of low-back pain: A randomised controlled trial
Methods	RCT; Target sample size: 440

ISRCTN47636118 (*Continued*)

Participants	Inclusion criteria: Patients are medically referred; patients presented no contraindication to Conventional physiotherapy (CPT) and Manipulative (MPT) physiotherapy; aged 18 to 65 years; low-back pain (LBP) not treated by physiotherapist in the previous month; duration of LBP at least 2 weeks before attending physiotherapy; patient's consent to participate in the randomised controlled trial; patient's agreement to be followed up to 12 months post-commencement of treatment Exclusion criteria: Does not meet inclusion criteria
Interventions	The objective of this trial was to compare the relative effectiveness of two common forms of physiotherapy: 1. Conventional Physiotherapy (CPT): consists of the use of electrical current, heat, cold, exercise and massage, and 2. Manipulative Physiotherapy (MPT): primarily consists of passive joint mobilisation and manipulative techniques, in the short and long term
Outcomes	The main outcome measures were disability, health and pain. These parameters were assessed by the: 1. Aberdeen Low-Back Pain Disability Scale 2. Current Perceived Health 42 (CPH42) Profile 3. Numerical Pain Scale (NRS). The NRS measures pain intensity from no pain to intolerable pain along an 11-point scale. The research assistants, who were blind to the treatment routine administered the questionnaires at baseline, then at 3, 6, and 12 weeks (short term) followed by 6, 9, 12 months (long term) after physiotherapy commenced
Starting date	January 2000; patient recruitment completed as of June 2008
Contact information	Dr ASL Leung; Department of Rehabilitation Sciences; The Hong Kong Polytechnic University
Notes	http://isrctn.org/ISRCTN47636118; status of this study is unknown and attempts to contact the primary investigator were unsuccessful Sponsored by: Hong Kong Health Services Research Fund (China)

NCT00376350

Trial name or title	Dose-response/Efficacy of manipulation for chronic low-back pain
Methods	RCT Target sample size: 400
Participants	Inclusion Criteria: 18 years and older with chronic LBP; current episode of low-back pain of mechanical origin; threshold low-back pain level Exclusion Criteria: Contraindications to spinal manipulation or massage; complicating conditions that could confound clinical outcome; prophylactic use of prescription medication; health-related litigation, claims, or disability compensation
Interventions	This study will determine the number of visits to a chiropractor for spinal manipulation, light massage, and ultrasound necessary for optimal relief of chronic low-back pain. The study will also determine the effectiveness of spinal manipulation

NCT00376350 (*Continued*)

Outcomes	Primary Outcome Measures: Modified Von Korff Pain Scale for low-back pain; Modified Von Korff Disability Scale (Time Frame: baseline, 2, 6, 12, 18, 24, 39, 52 weeks) Secondary Outcome Measures: Pain days; Disability days;Low-back pain unpleasantness; Fear avoidance beliefs; General health status/QoL; Healthcare utilization; Bias monitoring (Time Frame: baseline Baseline, 2; 6, 12, 18, 24, 39, 52 weeks); Patient satisfaction (Time Frame: 12 wk); Objective measures
Starting date	March 2007; estimated completion date March 2011
Contact information	Principal investigator, Mitchell Haas, DC
Notes	http://clinicaltrials.gov/show/NCT00376350 Primary sponsor: National Center for Complementary and Alternative Medicine (NCCAM)

ISRCTN61808774

Trial name or title	A randomised controlled trial of the effect on chronic low-back pain of a naturopathic osteopathy intervention
Methods	Random allocation to an intervention arm and usual care. Target sample size: 240
Participants	240 clients aged between 20 and 65 presenting at ten general practices in Brent in the summer of 2000 with low-back pain of over three months duration Exclusion criteria: not provided
Interventions	Questionnaire inquiry of disability, pain and sense of well being administered at recruitment, 3, 6, 12 months, and at 5 years. Half will be randomised to an intervention arm that comprises treatment at the British College of Naturopathy and Osteopathy (BCNO) by third/fourth year students under the supervision of experienced trainer practitioners. This intervention will be naturopathic osteopathy and include patient diaries. Up to seven treatments will be given, expecting an average of five weekly treatments
Outcomes	Assessment of: 1. Disability using the Roland Morris Score 2. Self competence using the Perceived Pain Management Competence Scale 3. Beliefs using the Back Beliefs Questionnaire 4. Pain using the Von Korff questionnaire 5. Well-being using the SF12. All of these are self-administered questionnaires.
Starting date	April 2000; recruitment completed; information last updated Nov. 2005
Contact information	Dr. Paul Thomas
Notes	http://isrctn.org/ISRCTN61808774. Sponsored by the Dept. of Health in the UK. Status unknown. Several attempts were made to contact the primary investigator

NCT00269321

Trial name or title	randomised clinical trial of chiropractic manual therapy plus home exercise, supervised exercise plus home exercise and home exercises alone for individuals 65 and over with chronic mechanical low-back pain Primary aims: to determine the relative clinical effectiveness the following treatments for LBP patients 65 years and older in both the short-term (after 12 weeks) and long-term (after 52 weeks), using LBP as the main outcome measure Secondary outcomes: to estimate the short- and long-term relative effectiveness of the three interventions using: 1. Patient-rated outcomes: low-back disability, general health status, patient satisfaction, improvement, and medication use measured by self-report questionnaires 2. Objective functional performance outcomes: spinal motion, trunk strength and endurance, and functional ability measured by examiners masked to treatment group assignment 3. Cost measures: direct and indirect costs of treatment measured by questionnaires, phone interviews, and medical records. 4. To describe elderly LBP patients' perceptions of treatment and the issues they consider when determining their satisfaction with care using qualitative methods nested within the RCT.
Methods	RCT Target sample size: 240
Participants	Inclusion Criteria: Sub-Acute and chronic low-back pain (Defined as current episode more than 6 weeks duration.); Quebec Task Force classifications 1, 2, 3 and 4. (This includes patients with back pain, stiffness or tenderness, with or without musculoskeletal signs and neurological signs.); 65 years of age and older; Independent ambulation; community dwelling (residency outside nursing home); score of 20 or more on Folstein Mini-Mental State Examination; stable prescription medication plan (no changes in prescription medications that affect musculoskeletal pain in previous month) Exclusion Criteria: Referred low-back pain from local joint lesions of the lower extremities or from visceral diseases; significant infectious disease determined by history or by referral to supplementary diagnostic tests; ongoing treatment for low-back pain by other health care providers; mean baseline low-back pain score of 20 percentage points or less; contraindications to exercise determined by history or by referral to supplementary diagnostic tests (i.e., uncontrolled arrhythmias, third degree heart block, recent ECG changes, unstable angina, acute myocardial infarction, acute congestive heart failure, cardiomyopathy, valvular heart disease, poorly controlled blood pressure, uncontrolled metabolic disease)'; contraindications to spinal manipulation (i.e. progressive neurological deficits blood clotting disorders; infectious and non-infectious inflammatory or destructive tissue changes of the spine; severe osteoporosis)
Interventions	1) Chiropractic Manual treatment + home exercise (procedure+behavior) 2) Supervised rehabilitative exercise+home exercise 3) Home exercise
Outcomes	Primary Outcome Measures: Patient-rated pain (0 to 11 box scale) (Time Frame: short term = 12 weeks; long term = 52 weeks) Secondary Outcome Measures: General Health; Disability; Improvement; Satisfaction; Medication use (Time Frame: short term = 12 weeks; long term = 52 weeks) Biomechanical test: Lumbar spinal motion Trunk strength & endurance; Functional Ability Observed Pain Behavior (Time Frame: short term = 12 weeks)
Starting date	October 2003; recruitment completed as of June 2008.

NCT00269321 (*Continued*)

Contact information	Principal investigator: Gert Brønfort, DC, PhD
Notes	http://clinicaltrials.gov/show/NCT00269321 Sponsored by: Northwestern Health Sciences University

NCT00269347

Trial name or title	Title: Manipulation, exercise and self-care for non-acute low-back pain Building upon the principal investigators' previous collaborative research, this randomised observer-blinded clinical trial will compare the following treatment for patients with non-acute low-back pain: 1. chiropractic spinal manipulation 2. rehabilitative exercise 3. self care education Theprimary aim is to examine the relative efficacy of the three interventions in terms of patient rated outcomes in the short-term (after 12 weeks) and the long-term (after 52 weeks) for non-acute low-back pain. Secondary aims include: 1. To examine the short and long-term relative cost effectiveness and cost utility of the three treatments. 2. To assess if there are clinically important differences between pre-specified subgroups of low-back pain patients. Subgroups are based on duration and current episode and radiating leg pain. 3. To evaluate if there treatment group differences in objective lumbar spine function (range of motion, strength and endurance) after 12 weeks of treatment and if changes in lumbar function are associated with changes in patient rated short and long-term outcomes. 4. To identify if baseline demographic or clinical variables can predict short or long-term outcome. 5. To describe patients' interpretations and perceptions of outcome measures used in clinical trials
Methods	RCT; Target sample size: 300
Participants	Inclusion criteria: patients are 18-65 years of age; Québec task force classification 1,2,3 and 4 (this includes patients with back pain, stiffness or tenderness, with or without musculoskeletal signs and neurological signs) ; primary complaint of back pain, with current episode greater than or equal to six weeks duration Exclusion criteria: previous lumbar spine surgery; back pain referred from local joint lesions of the lower extremities or from visceral diseases; progressive neurological deficits due to nerve root or spinal cord compression; aortic and peripheral vascular disease; existing cardiac disease requiring medical treatment; blood clotting disorders; diffuse idiopathic hyperostosis; infectious and noninfectious inflammatory or destructive tissue changes of the lumbar spine; presence of significant infectious disease, or other severe debilitating health problems; substance abuse; ongoing treatment for back pain by other health care providers; pregnant or nursing women; pain score of less than 30 percentage points; pending our current litigation
Interventions	1)Chiropractic Spinal Manipulation 2) Procedure: Exercise 3) Behavioral: Self-care
Outcomes	Primary Outcome Measures: Pain (Visual Analog Scale) at baseline, weeks 4,12,26,52 Secondary Outcome Measures: Disability (Modified Roland Scale); General Health (SF-36); Improvement (7 point scale); Disability (NHIS); Bothersomeness (7 point scale); Frequency (7 point scale); Satisfaction (5 point scale); Depression (CES-D); Medication use; Fear-avoidance (FABQ); Lumbar range of motion; Lumbar strength and endurance; Health care costs and utilization at baseline, weeks 4,12,26,52

NCT00269347 (*Continued*)

Starting date	January 2001; recruitment completed as of June 2008; currently in the review process
Contact information	Principal investigator: Gert Brønfort, DC, PhD
Notes	http://clinicaltrials.gov/show/NCT00269347 Sponsored by: Northwestern Health Sciences University

NCT00269503

Trial name or title	Official title: A Pilot Study of Chiropractic Prone Distraction for Subacute Back Pain With Sciatica
Methods	RCT; Target sample size: 60
Participants	Inclusion Criteria: active duty military personnel; aged 18-45 (age is limited to 45 years due to the natural aging and degeneration of the discs; the less hydration the disc maintain, the less likely manipulation will be successful); Have subacute low-back pain (more than three months duration but less than six months duration), with radicular component (sciatica) rated at a minimum level of 4 on the Numerical Rating Scale (NRS) of the Brief Pain Inventory; Have a confirmed herniated disc, as noted on MRI, which correlates with the clinical findings (sciatica) In this study, a "herniated disc" refers to any localized displacement of disc material, including nucleus, cartilage, fragmented apophyseal bone, or fragmented anular tissue, which results in back and leg pain. "Herniated Disc" also will include disc extrusions and disc bulges (protrusions) only when with associated annular tears In this study, "sciatica" refers to pain in the lower extremity(ies) that follows the course of the sciatic nerve Exclusion Criteria: patients who are not able to give informed consent; pregnant or nursing women; patients who have a primary bone disease, cancer, infection, spondylolysis or spondylolisthesis; patients who have had prior spine surgery, including rhizotomy; participation in another conflicting research study; patients who cannot commit to a trial lasting up to eight weeks or cannot come for bi-weekly treatments; patients who are going through a course of physical therapy or chiropractic treatment or at the time of planned enrolment or are being currently being managed and/or treated for any pain condition; patients who have an unstable medical or psychiatric condition; patients who are planning or have been advised to have spine surgery; any contraindications to either prone distraction or side posture manipulation will disqualify potential subjects from any participation in this study; patients with a pacemaker
Interventions	Conditions to be treated: Herniated Disc, lower back pain, sciatica. Procedures to be examined: prone distraction, side-posture manipulation, side-posture manipulation and prone distraction and usual care (control group)
Outcomes	Primary Outcome Measures: -Change in overall leg pain intensity, as assessed by the change, if any, of leg pain documented on the Numerical Rating Scale (NRS) in the Brief Pain Inventory (BPI) from baseline to 8 weeks -Time to pain relief, defined as NRS less than 4 after 2 consecutive visits Secondary Outcome Measures: -Change in overall back pain intensity, as assessed by the change, if any, of back pain documented on the BPI from baseline to 8 weeks -Change in overall pain intensity, as assessed by the change, if any, of the sum of back and leg pain documented on the BPI at measured intervals

NCT00269503 (*Continued*)

	-Change in overall pain intensity, as assessed by the change, if any, of the sum of back and leg pain documented on the BPI from baseline to 8 weeks -Patient satisfaction with treatment, as assessed by The Client Satisfaction Questionnaire -Medication use, as assessed by the Medication Log -Functional disability, as assessed by The Roland-Morris Low-Back Pain and Disability Questionnaire -Lost/decreased workdays -Change, if any, in percent of disc herniation, as determined by the study neuroradiologist -Descriptive changes in disc morphology, as assessed by the study neuroradiologist -Variability of treatment, as assessed by the number or prescriptions written, the number of visits to the Primary Care Clinic, as well as the number of referrals to additional treatments outside of the chiropractic clinic
Starting date	
Contact information	
Notes	Study terminated. No explanation offered. link: http://clinicaltrials.gov/show/nct00269503

DATA AND ANALYSES

Comparison 1. SMT vs. inert interventions

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Pain at 1 month	1	72	Mean Difference (IV, Random, 95% CI)	-6.0 [-15.82, 3.82]
1.2 Pain at 3 months	1	70	Mean Difference (IV, Random, 95% CI)	7.0 [-3.58, 17.58]
2 Perceived recovery	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.1 Recovery at 1 month	1	72	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.49, 2.19]
2.2 Recovery at 3 months	1	70	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.56, 1.65]
3 Return to work	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
3.1 Return to work at 1 month	1	72	Risk Ratio (M-H, Random, 95% CI)	1.29 [1.00, 1.65]
3.2 Return to work at 3 months	1	70	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.97, 1.40]

Comparison 2. SMT vs. sham SMT

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain	3		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Pain at 1 month	3	148	Mean Difference (IV, Random, 95% CI)	-3.24 [-13.62, 7.15]
1.2 Pain at 3 months	1	55	Mean Difference (IV, Random, 95% CI)	2.5 [-9.64, 14.64]
1.3 Pain at 6 months	1	51	Mean Difference (IV, Random, 95% CI)	7.10 [-5.16, 19.36]
2 Functional status	1		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 Functional status at 1 month	1	65	Std. Mean Difference (IV, Random, 95% CI)	-0.45 [-0.97, 0.06]
2.2 Functional status at 3 months	1	55	Std. Mean Difference (IV, Random, 95% CI)	0.0 [-0.56, 0.56]
2.3 Functional status at 6 months	1	51	Std. Mean Difference (IV, Random, 95% CI)	0.04 [-0.52, 0.61]

Comparison 3. SMT vs. any other intervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain	15		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Pain at 1 month	11	1894	Mean Difference (IV, Random, 95% CI)	-4.16 [-6.97, -1.36]
1.2 Pain at 3 months	10	1587	Mean Difference (IV, Random, 95% CI)	-2.54 [-6.13, 1.06]
1.3 Pain at 6 months	8	1594	Mean Difference (IV, Random, 95% CI)	-3.76 [-6.58, -0.95]
1.4 Pain at 12 months	7	1728	Mean Difference (IV, Random, 95% CI)	-0.89 [-2.92, 1.14]
2 Functional status	14		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 Functional status at 1 month	10	1820	Std. Mean Difference (IV, Random, 95% CI)	-0.22 [-0.36, -0.07]
2.2 Functional status at 3 months	10	1770	Std. Mean Difference (IV, Random, 95% CI)	-0.05 [-0.23, 0.13]
2.3 Functional status at 6 months	9	1806	Std. Mean Difference (IV, Random, 95% CI)	-0.12 [-0.22, -0.02]
2.4 Functional status at 12 months	8	1860	Std. Mean Difference (IV, Random, 95% CI)	-0.09 [-0.18, 0.00]
3 Perceived recovery	4		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
3.1 Recovery at 1 month	3	370	Risk Ratio (M-H, Random, 95% CI)	1.20 [1.04, 1.37]
3.2 Recovery at 3 months	2	182	Risk Ratio (M-H, Random, 95% CI)	1.70 [1.20, 2.40]
3.3 Recovery at 6 months	1	112	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.81, 1.38]
3.4 Recovery at 12 months	1	109	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.87, 1.55]
4 Return to work	4		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
4.1 Return to work at 1 month	1	71	Risk Ratio (M-H, Random, 95% CI)	1.10 [0.91, 1.35]
4.2 Return to work at 3 months	2	188	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.93, 1.14]
4.3 Return to work at 12 months	3	389	Risk Ratio (M-H, Random, 95% CI)	1.09 [0.98, 1.21]
5 Health-related Quality of Life	4		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
5.1 Health-related quality of life at 1 month	3	361	Std. Mean Difference (IV, Random, 95% CI)	-0.08 [-0.29, 0.13]
5.2 Health-related quality of life at 3 months	3	246	Std. Mean Difference (IV, Random, 95% CI)	0.21 [-0.27, 0.70]
5.3 Health-related quality of life at 12 months	1	31	Std. Mean Difference (IV, Random, 95% CI)	1.00 [-1.75, -0.24]

Comparison 4. Subset of comparison 3. SMT vs. ineffective interventions

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain	4		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Pain at 1 month	3	277	Mean Difference (IV, Random, 95% CI)	-8.02 [-16.14, 0.10]
1.2 Pain at 3 months	2	147	Mean Difference (IV, Random, 95% CI)	-4.59 [-17.20, 8.03]
1.3 Pain at 6 months	3	242	Mean Difference (IV, Random, 95% CI)	-8.92 [-13.43, -4.41]

1.4 Pain at 12 months	1	82	Mean Difference (IV, Random, 95% CI)	-5.0 [-12.46, 2.46]
2 Functional status	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 Functional status at 1 month	2	206	Std. Mean Difference (IV, Random, 95% CI)	-0.47 [-0.85, -0.09]
2.2 Functional status at 3 months	1	82	Std. Mean Difference (IV, Random, 95% CI)	0.64 [0.19, 1.08]
2.3 Functional status at 6 months	3	243	Std. Mean Difference (IV, Random, 95% CI)	-0.28 [-0.56, 0.01]
2.4 Functional status at 12 months	1	82	Std. Mean Difference (IV, Random, 95% CI)	0.0 [-0.43, 0.43]
3 Perceived recovery	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
3.1 Recovery at 1 month	1	71	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.48, 2.12]
3.2 Recovery at 3 months	1	65	Risk Ratio (M-H, Random, 95% CI)	1.42 [0.71, 2.83]
4 Return to work	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
4.1 Return to work at 1 month	1	71	Risk Ratio (M-H, Random, 95% CI)	1.10 [0.91, 1.35]
4.2 Return to work at 3 months	1	65	Risk Ratio (M-H, Random, 95% CI)	1.02 [0.90, 1.17]

Comparison 5. Subset of comparison 3. SMT vs. effective interventions

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain	13		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Pain at 1 month	9	1663	Mean Difference (IV, Random, 95% CI)	-3.04 [-5.98, -0.10]
1.2 Pain at 3 months	9	1484	Mean Difference (IV, Random, 95% CI)	-2.09 [-6.29, 2.11]
1.3 Pain at 6 months	7	1436	Mean Difference (IV, Random, 95% CI)	-2.24 [-5.25, 0.78]
1.4 Pain at 12 months	7	1690	Mean Difference (IV, Random, 95% CI)	-0.52 [-2.57, 1.53]
2 Functional status	13		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 Functional status at 1 month	9	1660	Std. Mean Difference (IV, Random, 95% CI)	-0.17 [-0.31, -0.03]
2.2 Functional status at 3 months	10	1732	Std. Mean Difference (IV, Random, 95% CI)	-0.10 [-0.27, 0.06]
2.3 Functional status at 6 months	8	1647	Std. Mean Difference (IV, Random, 95% CI)	-0.09 [-0.19, 0.02]
2.4 Functional status at 12 months	8	1822	Std. Mean Difference (IV, Random, 95% CI)	-0.11 [-0.22, 0.00]
3 Perceived recovery	3		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
3.1 Recovery at 1 month	2	299	Risk Ratio (M-H, Random, 95% CI)	1.20 [1.05, 1.38]
3.2 Recovery at 3 months	1	117	Risk Ratio (M-H, Random, 95% CI)	1.80 [1.21, 2.69]
3.3 Recovery at 6 months	1	112	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.81, 1.38]
3.4 Recovery at 12 months	1	109	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.87, 1.55]
4 Return to work	3		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
4.1 Return to work at 3 months	1	123	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.89, 1.21]
4.2 Return to work at 12 months	3	389	Risk Ratio (M-H, Random, 95% CI)	1.09 [0.98, 1.21]
5 Health-related Quality of Life	4		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only

5.1 Health-related quality of life at 1 month	3	361	Std. Mean Difference (IV, Random, 95% CI)	-0.08 [-0.29, 0.13]
5.2 Health-related quality of life at 3 months	3	246	Std. Mean Difference (IV, Random, 95% CI)	0.21 [-0.27, 0.70]
5.3 Health-related quality of life at 12 months	1	31	Std. Mean Difference (IV, Random, 95% CI)	1.00 [-1.75, -0.24]

Comparison 6. SMT + intervention vs. intervention alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain	4		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Pain at 1 month	3	228	Mean Difference (IV, Random, 95% CI)	-5.88 [-10.85, -0.90]
1.2 Pain at 3 months	2	1016	Mean Difference (IV, Random, 95% CI)	-7.23 [-11.72, -2.74]
1.3 Pain at 6 months	2	143	Mean Difference (IV, Random, 95% CI)	-6.77 [-14.07, 0.53]
1.4 Pain at 12 months	2	1000	Mean Difference (IV, Random, 95% CI)	-3.31 [-6.60, -0.02]
2 Functional status	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 Functional status at 1 month	2	156	Std. Mean Difference (IV, Random, 95% CI)	-0.40 [-0.73, -0.07]
2.2 Functional status at 3 months	2	1078	Std. Mean Difference (IV, Random, 95% CI)	-0.22 [-0.38, -0.06]
2.3 Functional status at 6 months	2	142	Std. Mean Difference (IV, Random, 95% CI)	-0.30 [-0.64, 0.03]
2.4 Functional status at 12 months	1	994	Std. Mean Difference (IV, Random, 95% CI)	-0.21 [-0.34, -0.09]
3 Perceived recovery	1	32	Risk Ratio (M-H, Random, 95% CI)	3.4 [1.12, 10.28]
3.1 Recovery at 1 month	1	32	Risk Ratio (M-H, Random, 95% CI)	3.4 [1.12, 10.28]

Comparison 7. Subset of comparison 3. SMT vs. any other intervention - studies w/ low RoB only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain	8		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Pain at 1 month	6	1405	Mean Difference (IV, Random, 95% CI)	-2.76 [-5.19, -0.32]
1.2 Pain at 3 months	5	1074	Mean Difference (IV, Random, 95% CI)	-4.55 [-8.68, -0.43]
1.3 Pain at 6 months	4	1105	Mean Difference (IV, Random, 95% CI)	-3.07 [-5.42, -0.71]
1.4 Pain at 12 months	3	1285	Mean Difference (IV, Random, 95% CI)	-0.76 [-3.19, 1.66]
2 Functional status	8		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 Functional status at 1 month	6	1402	Std. Mean Difference (IV, Random, 95% CI)	-0.17 [-0.29, -0.06]
2.2 Functional status at 3 months	6	1323	Std. Mean Difference (IV, Random, 95% CI)	-0.18 [-0.37, 0.01]
2.3 Functional status at 6 months	5	1313	Std. Mean Difference (IV, Random, 95% CI)	-0.12 [-0.23, -0.00]

2.4 Functional status at 12 months	4	1418	Std. Mean Difference (IV, Random, 95% CI)	-0.06 [-0.16, 0.05]
3 Perceived recovery	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
3.1 Recovery at 1 month	1	113	Risk Ratio (M-H, Random, 95% CI)	1.18 [0.93, 1.50]
3.2 Recovery at 6 months	1	112	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.81, 1.38]
3.3 Recovery at 12 months	1	109	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.87, 1.55]
4 Return to work	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
4.1 Return to work at 3 months	1	123	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.89, 1.21]
4.2 Return to work at 12 months	2	198	Risk Ratio (M-H, Random, 95% CI)	1.06 [0.86, 1.31]
5 Health-related Quality of Life	1		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
5.1 Health-related quality of life at 1 month	1	105	Std. Mean Difference (IV, Random, 95% CI)	-0.17 [-0.55, 0.22]
5.2 Health-related quality of life at 3 months	1	96	Std. Mean Difference (IV, Random, 95% CI)	-0.02 [-0.42, 0.39]

Comparison 8. Subset of comparisons 1, 2 & 3. SMT vs. ineffective/sham/inert interventions

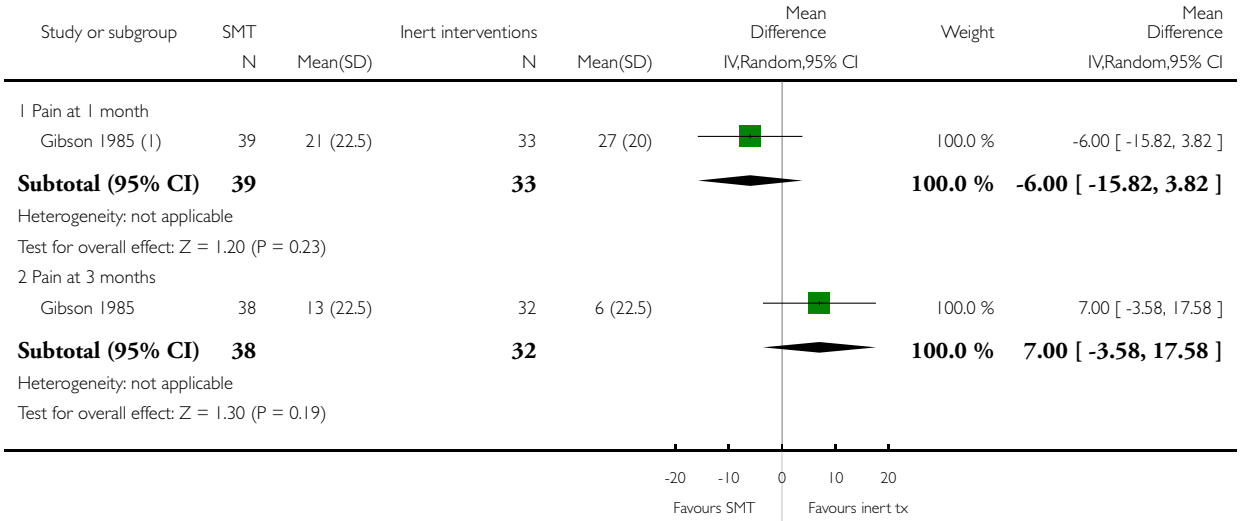
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain	7		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Pain at 1 month	6	459	Mean Difference (IV, Random, 95% CI)	-6.07 [-11.52, -0.62]
1.2 Pain at 3 months	3	234	Mean Difference (IV, Random, 95% CI)	0.14 [-6.16, 6.44]
1.3 Pain at 6 months	4	293	Mean Difference (IV, Random, 95% CI)	-6.04 [-12.94, 0.85]
1.4 Pain at 12 months	1	82	Mean Difference (IV, Random, 95% CI)	-5.0 [-12.46, 2.46]
2 Functional status	4		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 Functional status at 1 month	3	271	Std. Mean Difference (IV, Random, 95% CI)	-0.47 [-0.72, -0.23]
2.2 Functional status at 3 months	2	137	Std. Mean Difference (IV, Random, 95% CI)	0.34 [-0.28, 0.96]
2.3 Functional status at 6 months	4	294	Std. Mean Difference (IV, Random, 95% CI)	-0.22 [-0.47, 0.03]
2.4 Functional status at 12 months	1	82	Std. Mean Difference (IV, Random, 95% CI)	0.0 [-0.43, 0.43]

Analysis 1.1. Comparison 1 SMT vs. inert interventions, Outcome 1 Pain.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 1 SMT vs. inert interventions

Outcome: 1 Pain



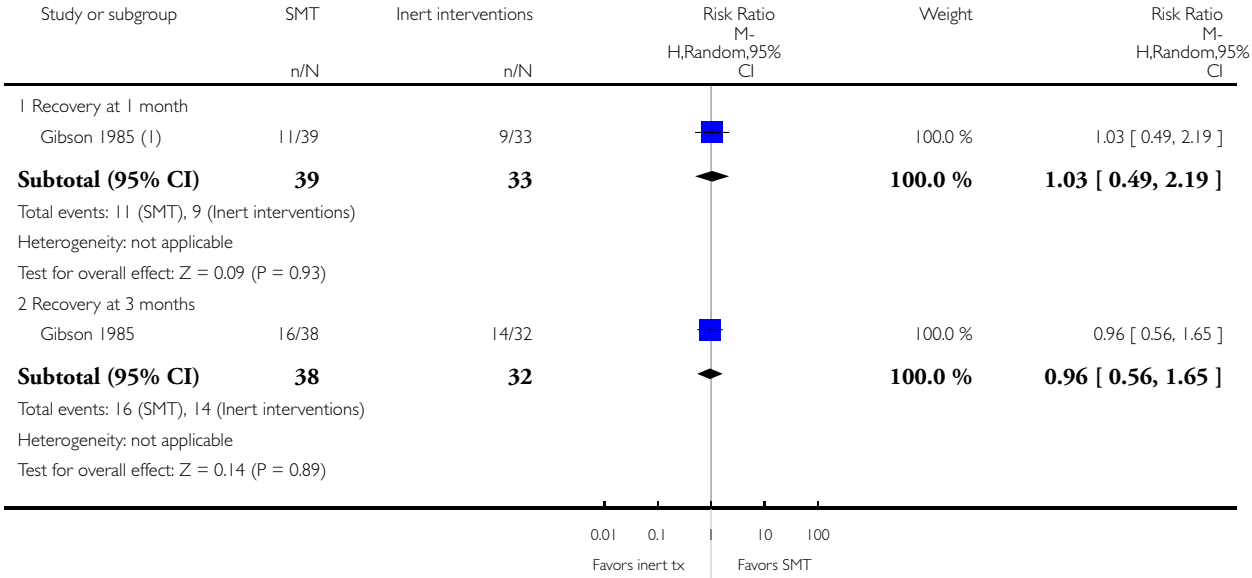
(1) OMT vs. detuned diathermy; median (range) presented in study - and converted; daytime pain

Analysis 1.2. Comparison 1 SMT vs. inert interventions, Outcome 2 Perceived recovery.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 1 SMT vs. inert interventions

Outcome: 2 Perceived recovery



(1) Osteopathic SMT vs. detuned diathermy; number of patients pain free

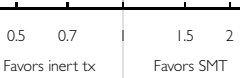
Analysis 1.3. Comparison 1 SMT vs. inert interventions, Outcome 3 Return to work.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 1 SMT vs. inert interventions

Outcome: 3 Return to work

Study or subgroup	SMT n/N	Inert interventions n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Return to work at 1 month					
Gibson 1985 (1)	35/39	23/33		100.0 %	1.29 [1.00, 1.65]
Subtotal (95% CI)	**39**	**33**		**100.0 %**	**1.29 [1.00, 1.65]**
Total events: 35 (SMT), 23 (Inert interventions)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.99 (P = 0.046)					
2 Return to work at 3 months					
Gibson 1985	36/38	26/32		100.0 %	1.17 [0.97, 1.40]
Subtotal (95% CI)	**38**	**32**		**100.0 %**	**1.17 [0.97, 1.40]**
Total events: 36 (SMT), 26 (Inert interventions)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.65 (P = 0.099)					



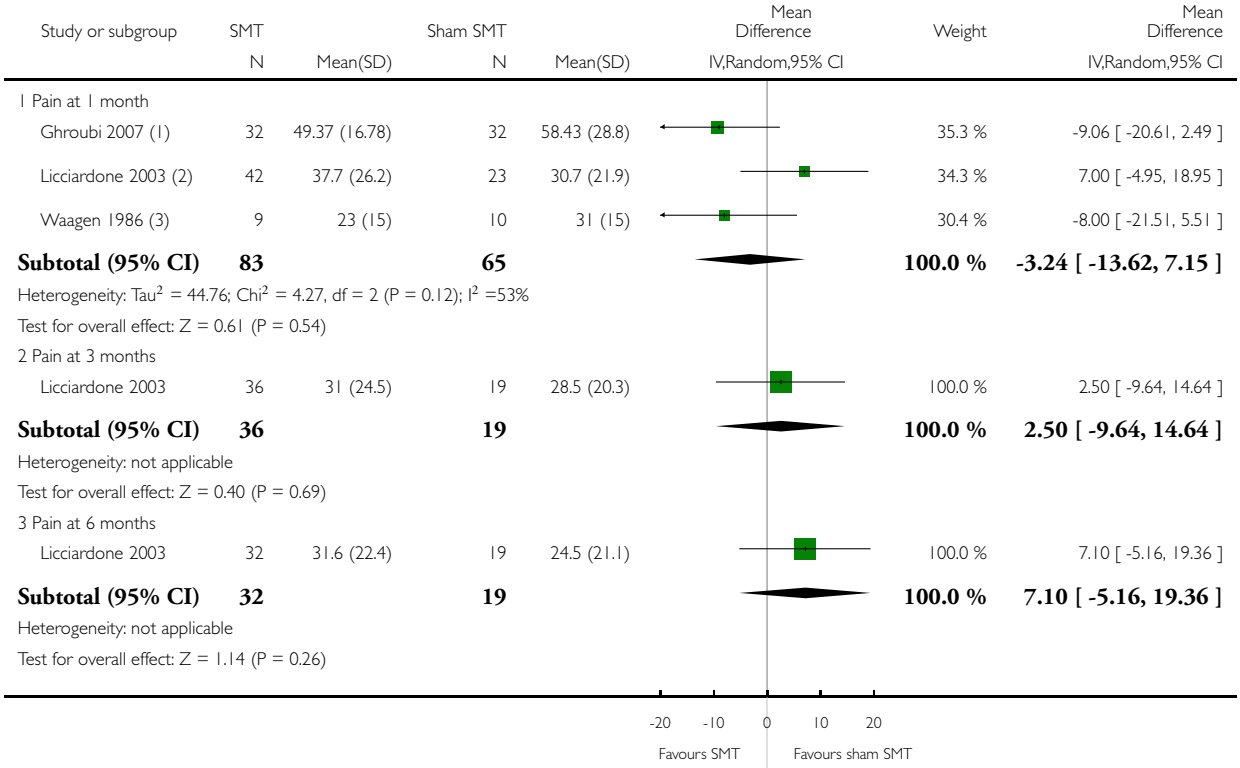
(1) Osteopathic SMT vs. detuned diathermy; number able to work or with unrestricted activities

Analysis 2.1. Comparison 2 SMT vs. sham SMT, Outcome 1 Pain.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 2 SMT vs. sham SMT

Outcome: 1 Pain



(1) Unclear SMT vs. sham SMT

(2) Osteopathic SMT vs. sham SMT

(3) Chiropractic/HVLA SMT vs. sham SMT; no measure of variation was presented; SD's presented here are approximated from similar populations

Analysis 2.2. Comparison 2 SMT vs. sham SMT, Outcome 2 Functional status.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 2 SMT vs. sham SMT

Outcome: 2 Functional status

Study or subgroup	SMT N	Mean(SD)	Sham SMT N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
1 Functional status at 1 month							
Licciardone 2003 (1)	42	5.7 (4.1)	23	7.7 (4.8)		100.0 %	-0.45 [-0.97, 0.06]
Subtotal (95% CI)	**42**		**23**			**100.0 %**	**-0.45 [-0.97, 0.06]**
Heterogeneity: not applicable							
Test for overall effect: Z = 1.73 (P = 0.084)							
2 Functional status at 3 months							
Licciardone 2003	36	6.1 (4.5)	19	6.1 (4.1)		100.0 %	0.0 [-0.56, 0.56]
Subtotal (95% CI)	**36**		**19**			**100.0 %**	**0.0 [-0.56, 0.56]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.0 (P = 1.0)							
3 Functional status at 6 months							
Licciardone 2003	32	5.2 (4.5)	19	5 (4.5)		100.0 %	0.04 [-0.52, 0.61]
Subtotal (95% CI)	**32**		**19**			**100.0 %**	**0.04 [-0.52, 0.61]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.15 (P = 0.88)							

(1) Osteopathic SMT

Analysis 3.1. Comparison 3 SMT vs. any other intervention, Outcome 1 Pain.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 3 SMT vs. any other intervention

Outcome: 1 Pain

Study or subgroup	SMT N	SMT Mean(SD)	Other intervention N	Other intervention Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Pain at 1 month							
Brnfort 1996 (1)	62	34 (19)	43	36 (22)		6.5 %	-2.00 [-10.10, 6.10]
Gibson 1985 (2)	39	21 (22.5)	32	28 (24)		4.5 %	-7.00 [-17.91, 3.91]
Gudavalli 2006 (3)	123	17.4 (22.3)	112	23.4 (20.7)		9.2 %	-6.00 [-11.50, -0.50]
Hemmila 2002 (4)	22	30.5 (15)	34	27 (15)		6.6 %	3.50 [-4.54, 11.54]
Hemmila 2002 (5)	22	30.5 (15)	35	30 (15)		6.6 %	0.50 [-7.50, 8.50]
Hondras 2009 (6)	83	27.63 (19.31)	16	33.47 (19.49)		4.8 %	-5.84 [-16.25, 4.57]
Hondras 2009 (7)	90	29.49 (19.29)	16	33.47 (19.49)		4.9 %	-3.98 [-14.33, 6.37]
Hsieh 2002 (8)	22	25.8 (19.3)	42	21.3 (12.8)		5.8 %	4.50 [-4.45, 13.45]
Hsieh 2002 (9)	22	25.8 (19.3)	49	27.8 (18.2)		5.4 %	-2.00 [-11.54, 7.54]
Hurwitz 2002 (10)	169	31 (18)	168	35 (20)		11.0 %	-4.00 [-8.06, 0.06]
Hurwitz 2002 (11)	169	34 (19)	169	36 (19)		11.0 %	-2.00 [-6.05, 2.05]
Mohseni-Bandpei 2006 (12)	56	23.4 (19)	56	37.9 (19)		7.5 %	-14.50 [-21.54, -7.46]
Rasmussen-Barr 2003 (13)	19	24 (26.7)	22	20 (17.8)		3.1 %	4.00 [-10.12, 18.12]
Skillgate 2007 (14)	92	36 (14.4)	80	44 (13.4)		10.9 %	-8.00 [-12.16, -3.84]
Wilkey 2008 (15)	18	42.8 (22.5)	12	70 (24.1)		2.3 %	-27.20 [-44.35, -10.05]
Subtotal (95% CI)	**1008**		**886**			**100.0 %**	**-4.16 [-6.97, -1.36]**
Heterogeneity: Tau^2 = 14.40; Chi^2 = 30.48, df = 14 (P = 0.01); I^2 =54%							
Test for overall effect: Z = 2.91 (P = 0.0037)							
2 Pain at 3 months							
Brnfort 1996	56	27 (20)	40	35 (22)		7.6 %	-8.00 [-16.60, 0.60]
Ferreira 2007 (16)	77	41 (26)	147	44 (24.5)		8.8 %	-3.00 [-10.03, 4.03]
Gibson 1985	38	13 (22.5)	27	25 (22.5)		5.9 %	-12.00 [-23.10, -0.90]
Gudavalli 2006	87	21.5 (22.3)	76	23.7 (20.7)		9.2 %	-2.20 [-8.80, 4.40]
Hemmila 2002 (17)	22	30 (15)	35	31 (15)		8.0 %	-1.00 [-9.00, 7.00]
Hemmila 2002 (18)	22	30 (15)	34	27.5 (15)		8.0 %	2.50 [-5.54, 10.54]
Paatelma 2008 (19)	23	18 (12.6)	37	17 (13.3)		9.1 %	1.00 [-5.70, 7.70]
Paatelma 2008 (20)	23	18 (12.6)	52	10 (14.8)		9.3 %	8.00 [1.47, 14.53]

(34) + advice

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Study or subgroup	SMT N	SMT Mean(SD)	Other intervention N	Other intervention Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
Rasmussen-Barr 2003	16	22 (28.1)	17	14 (14.1)		3.9 %	8.00 [-7.31, 23.31]
Skillgate 2007	89	26 (14.4)	73	37 (13.4)		11.2 %	-11.00 [-15.29, -6.71]
UK BEAM trial 2004 (21)	275	40.9 (24.87)	204	44.73 (24.42)		11.1 %	-3.83 [-8.29, 0.63]
Zaproudina 2009 (22)	57	23.4 (23.9)	60	28 (20.9)		7.9 %	-4.60 [-12.75, 3.55]
Subtotal (95% CI)	**785**		**802**			**100.0 %**	**-2.54 [-6.13, 1.06]**
Heterogeneity: Tau² = 25.18; Chi² = 33.61, df = 11 (P = 0.00042); I² =67%							
Test for overall effect: Z = 1.38 (P = 0.17)							
3 Pain at 6 months							
Ferreira 2007	72	43 (26)	139	45.6 (26)		8.0 %	-2.60 [-10.00, 4.80]
Gudavalli 2006	90	19.7 (22.3)	74	26.8 (20.7)		9.0 %	-7.10 [-13.69, -0.51]
Hemmila 2002 (23)	22	25 (15)	35	30 (15)		7.3 %	-5.00 [-13.00, 3.00]
Hemmila 2002 (24)	22	25 (15)	34	26 (15)		7.2 %	-1.00 [-9.04, 7.04]
Hsieh 2002 (25)	20	24 (24.1)	47	29.9 (22.8)		4.0 %	-5.90 [-18.31, 6.51]
Hsieh 2002 (26)	20	24 (24.1)	42	22.9 (19.8)		4.1 %	1.10 [-11.04, 13.24]
Hurwitz 2002 (27)	163	18 (18)	159	22 (20)		12.7 %	-4.00 [-8.16, 0.16]
Hurwitz 2002 (28)	165	26 (19)	165	28.5 (19)		12.8 %	-2.50 [-6.60, 1.60]
Mohseni-Bandpei 2006	40	27.1 (19)	33	40.2 (19)		6.5 %	-13.10 [-21.86, -4.34]
Paatelma 2008 (29)	23	14 (8.1)	52	10 (7.4)		13.2 %	4.00 [0.13, 7.87]
Paatelma 2008 (30)	23	14 (8.1)	37	22 (17.8)		8.9 %	-8.00 [-14.62, -1.38]
Zaproudina 2009	57	24.5 (24.6)	60	31.3 (25.6)		6.2 %	-6.80 [-15.90, 2.30]
Subtotal (95% CI)	**717**		**877**			**100.0 %**	**-3.76 [-6.58, -0.95]**
Heterogeneity: Tau² = 11.71; Chi² = 23.36, df = 11 (P = 0.02); I² =53%							
Test for overall effect: Z = 2.62 (P = 0.0089)							
4 Pain at 12 months							
Ferreira 2007	73	49 (27)	138	50.6 (28.5)		6.7 %	-1.60 [-9.41, 6.21]
Gudavalli 2006	96	20.9 (22.3)	78	23.3 (20.7)		10.0 %	-2.40 [-8.80, 4.00]
Hurwitz 2002 (31)	156	27.5 (18)	148	28 (20)		22.4 %	-0.50 [-4.78, 3.78]
Hurwitz 2002 (32)	153	32.5 (19)	153	34 (19)		22.7 %	-1.50 [-5.76, 2.76]
Paatelma 2008 (33)	23	11 (14.1)	52	8 (17)		7.5 %	3.00 [-4.39, 10.39]
Paatelma 2008 (34)	23	11 (14.1)	37	16 (19.3)		5.7 %	-5.00 [-13.48, 3.48]
Rasmussen-Barr 2003	14	18 (21.5)	17	13 (13.3)		2.5 %	5.00 [-7.92, 17.92]
UK BEAM trial 2004	264	41.68 (25.67)	200	41.54 (26.02)		18.2 %	0.14 [-4.61, 4.89]
Zaproudina 2009	50	26.6 (26.2)	53	30.7 (23.9)		4.4 %	-4.10 [-13.80, 5.60]
Subtotal (95% CI)	**852**		**876**			**100.0 %**	**-0.89 [-2.92, 1.14]**
Heterogeneity: Tau² = 0.0; Chi² = 3.72, df = 8 (P = 0.88); I² =0.0%							
(34) + advice							

(*Continued* . . .)

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Study or subgroup	SMT N	Mean(SD)	Other intervention N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI

Test for overall effect: Z = 0.86 (P = 0.39)

(1) HVLA-SMT + strength exercises vs. NSAID + strength exercises;

(2) SMT vs. diathermy; median (range) presented in text - and converted; daytime pain

(3) SMT (flexion-distraction) vs. exercise; ITT data; change scores presented - used SD from baseline

(4) Bone setting vs. physiotherapy; data from 1997 publication; mean data estimated from figure (6 wks) - no SD presented in the publ.; SD est. from other studies

(5) Bone setting vs. exercise; data from 1997 publication; mean data estimated from figure (6 wks) - no SD presented in the publ.; SD est. from other studies

(6) LVVA-SMT (flexion-distraction) vs. medical care; adjusted scores from linear effects model; data from author

(7) HVLA-SMT vs medical care; adjusted scores from linear effects model; data from author

(8) SMT vs. Back school

(9) SMT vs. Myofascial therapy

(10) chiropractic care +physical modalities (DCPm) vs. medical care + physical therapy (MDpt); data from 6 weeks; average pain; data estimated from graphs; SD used from baseline

(11) chiropractic care only vs. medical care only; data from 6 weeks; average pain; data estimated from graphs; SD used from baseline

(12) SMT + exercise vs. Ultrasound + exercise

(13) Manual therapy vs. stabilizing training

(14) Naprapathy vs. std. medical care; data provided by author

(15) "chiropractic management" vs. outpatient hospital pain clinic

(16) SMT vs. general and motor exercise (combined)

(17) vs. exercise

(18) vs. physiotherapy

(19) OMT vs. Advice-group (counseling session + educational back booklet)

(20) OMT vs. McKenzie; VAS; median (IQR) - converted to mean (SD)

(21) Best care + SMT vs. Best care + exercise; Modified von Korff - pain subscale only

(22) Bone-setting vs. physiotherapy; VAS; data provided by primary author; one month post-tx. = 3 months

(23) vs. exercise

(24) vs. physiotherapy

(25) vs. myofascial therapy

(26) vs. back school

(27) + physiotherapy modalities

(28) vs. MD care only

(29) vs. McKenzie

(30) vs. advice

(31) + physiotherapy modalities

(32) vs. MD care only

(33) + McKenzie

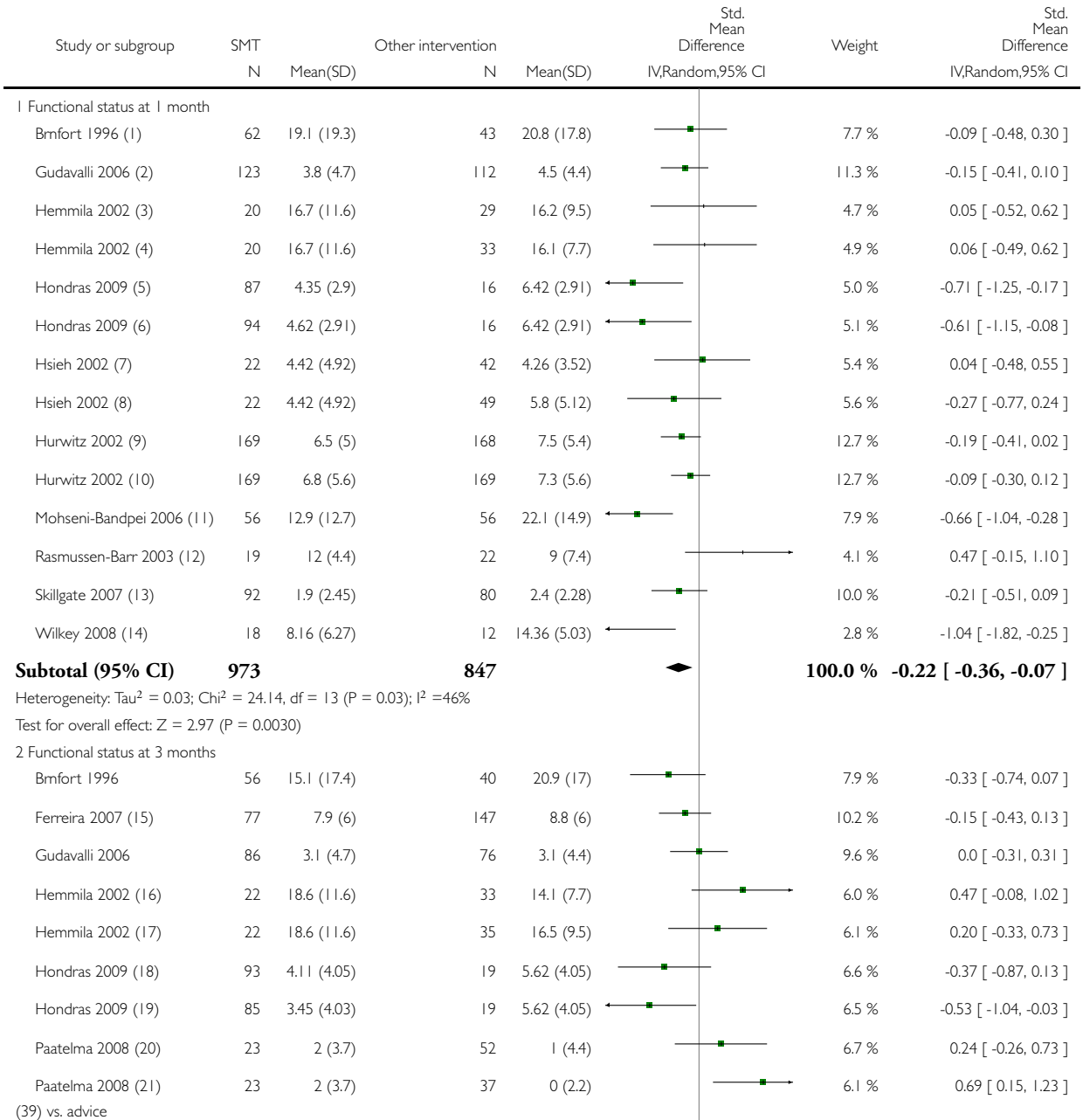
(34) + advice

Analysis 3.2. Comparison 3 SMT vs. any other intervention, Outcome 2 Functional status.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 3 SMT vs. any other intervention

Outcome: 2 Functional status



Study or subgroup	SMT N	Mean(SD)	Other intervention N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
1 Functional status at 1 month							
Brnfort 1996 (1)	62	19.1 (19.3)	43	20.8 (17.8)		7.7 %	-0.09 [-0.48, 0.30]
Gudavalli 2006 (2)	123	3.8 (4.7)	112	4.5 (4.4)		11.3 %	-0.15 [-0.41, 0.10]
Hemmila 2002 (3)	20	16.7 (11.6)	29	16.2 (9.5)		4.7 %	0.05 [-0.52, 0.62]
Hemmila 2002 (4)	20	16.7 (11.6)	33	16.1 (7.7)		4.9 %	0.06 [-0.49, 0.62]
Hondras 2009 (5)	87	4.35 (2.9)	16	6.42 (2.91)		5.0 %	-0.71 [-1.25, -0.17]
Hondras 2009 (6)	94	4.62 (2.91)	16	6.42 (2.91)		5.1 %	-0.61 [-1.15, -0.08]
Hsieh 2002 (7)	22	4.42 (4.92)	42	4.26 (3.52)		5.4 %	0.04 [-0.48, 0.55]
Hsieh 2002 (8)	22	4.42 (4.92)	49	5.8 (5.12)		5.6 %	-0.27 [-0.77, 0.24]
Hurwitz 2002 (9)	169	6.5 (5)	168	7.5 (5.4)		12.7 %	-0.19 [-0.41, 0.02]
Hurwitz 2002 (10)	169	6.8 (5.6)	169	7.3 (5.6)		12.7 %	-0.09 [-0.30, 0.12]
Mohseni-Bandpei 2006 (11)	56	12.9 (12.7)	56	22.1 (14.9)		7.9 %	-0.66 [-1.04, -0.28]
Rasmussen-Barr 2003 (12)	19	12 (4.4)	22	9 (7.4)		4.1 %	0.47 [-0.15, 1.10]
Skillgate 2007 (13)	92	1.9 (2.45)	80	2.4 (2.28)		10.0 %	-0.21 [-0.51, 0.09]
Wilkey 2008 (14)	18	8.16 (6.27)	12	14.36 (5.03)		2.8 %	-1.04 [-1.82, -0.25]
Subtotal (95% CI)	**973**		**847**			**100.0 %**	**-0.22 [-0.36, -0.07]**
Heterogeneity: Tau² = 0.03; Chi² = 24.14, df = 13 (P = 0.03); I² =46%							
Test for overall effect: Z = 2.97 (P = 0.0030)							
2 Functional status at 3 months							
Brnfort 1996	56	15.1 (17.4)	40	20.9 (17)		7.9 %	-0.33 [-0.74, 0.07]
Ferreira 2007 (15)	77	7.9 (6)	147	8.8 (6)		10.2 %	-0.15 [-0.43, 0.13]
Gudavalli 2006	86	3.1 (4.7)	76	3.1 (4.4)		9.6 %	0.0 [-0.31, 0.31]
Hemmila 2002 (16)	22	18.6 (11.6)	33	14.1 (7.7)		6.0 %	0.47 [-0.08, 1.02]
Hemmila 2002 (17)	22	18.6 (11.6)	35	16.5 (9.5)		6.1 %	0.20 [-0.33, 0.73]
Hondras 2009 (18)	93	4.11 (4.05)	19	5.62 (4.05)		6.6 %	-0.37 [-0.87, 0.13]
Hondras 2009 (19)	85	3.45 (4.03)	19	5.62 (4.05)		6.5 %	-0.53 [-1.04, -0.03]
Paatelma 2008 (20)	23	2 (3.7)	52	1 (4.4)		6.7 %	0.24 [-0.26, 0.73]
Paatelma 2008 (21)	23	2 (3.7)	37	0 (2.2)		6.1 %	0.69 [0.15, 1.23]

(39) vs. advice

(*Continued . . .*)

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Study or subgroup	SMT N	SMT Mean(SD)	Other intervention N	Other intervention Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
Rasmussen-Barr 2003	16	13 (12.6)	17	6 (4.4)		4.3 %	0.73 [0.02, 1.44]
Skillgate 2007	90	1.3 (2.45)	73	2.4 (2.28)		9.5 %	-0.46 [-0.77, -0.15]
UK BEAM trial 2004 (22)	287	5.09 (4.74)	225	5.47 (4.35)		11.9 %	-0.08 [-0.26, 0.09]
Zaproudina 2009 (23)	57	12.2 (10.9)	60	15.9 (10.1)		8.6 %	-0.35 [-0.72, 0.02]
Subtotal (95% CI)	**937**		**833**			**100.0 %**	**-0.05 [-0.23, 0.13]**
Heterogeneity: Tau² = 0.06; Chi² = 33.55, df = 12 (P = 0.00079); I² =64%							
Test for overall effect: Z = 0.60 (P = 0.55)							
3 Functional status at 6 months							
Ferreira 2007	72	7.7 (6.2)	139	9.3 (6.7)		11.5 %	-0.24 [-0.53, 0.04]
Gudavalli 2006	90	2.8 (4.7)	78	3.4 (4.4)		10.1 %	-0.13 [-0.43, 0.17]
Hemmila 2002 (24)	22	14.3 (11.6)	33	13.4 (7.7)		3.2 %	0.09 [-0.45, 0.63]
Hemmila 2002 (25)	22	14.3 (11.6)	33	15.9 (9.5)		3.2 %	-0.15 [-0.69, 0.39]
Hondras 2009 (26)	89	4.06 (4.36)	17	5.34 (4.27)		3.5 %	-0.29 [-0.81, 0.23]
Hondras 2009 (27)	86	3.44 (4.39)	17	5.34 (4.27)		3.4 %	-0.43 [-0.96, 0.09]
Hsieh 2002 (28)	21	3.29 (4.73)	42	3.48 (3.86)		3.4 %	-0.05 [-0.57, 0.48]
Hsieh 2002 (29)	21	3.29 (4.73)	47	5.06 (4.78)		3.5 %	-0.37 [-0.89, 0.15]
Hurwitz 2002 (30)	165	4.1 (5.6)	165	4.8 (5.6)		20.0 %	-0.12 [-0.34, 0.09]
Hurwitz 2002 (31)	163	3.8 (5)	159	3.5 (5.4)		19.6 %	0.06 [-0.16, 0.28]
Mohseni-Bandpei 2006	40	14.1 (12.7)	33	20.7 (14.9)		4.3 %	-0.48 [-0.94, -0.01]
Paatelma 2008 (32)	23	1 (3)	37	1 (5.2)		3.5 %	0.0 [-0.52, 0.52]
Paatelma 2008 (33)	23	1 (3)	52	0 (3)		3.8 %	0.33 [-0.16, 0.82]
Zaproudina 2009	57	12.2 (12.1)	60	14.5 (8.9)		7.1 %	-0.22 [-0.58, 0.15]
Subtotal (95% CI)	**894**		**912**			**100.0 %**	**-0.12 [-0.22, -0.02]**
Heterogeneity: Tau² = 0.0; Chi² = 12.50, df = 13 (P = 0.49); I² =0.0%							
Test for overall effect: Z = 2.41 (P = 0.016)							
4 Functional status at 12 months							
Ferreira 2007	73	9.2 (6.6)	138	9.2 (6.7)		10.6 %	0.0 [-0.28, 0.28]
Gudavalli 2006	95	2.7 (4.7)	78	3.1 (4.4)		9.5 %	-0.09 [-0.39, 0.21]
Hemmila 2002 (34)	22	15.3 (11.6)	32	17.2 (9.5)		2.9 %	-0.18 [-0.72, 0.36]
Hemmila 2002 (35)	22	15.3 (11.6)	32	13.7 (7.7)		2.9 %	0.17 [-0.38, 0.71]
Hurwitz 2002 (36)	153	6.6 (5.6)	153	7.1 (5.6)		16.9 %	-0.09 [-0.31, 0.14]
Hurwitz 2002 (37)	156	6.2 (5)	148	6 (5.4)		16.8 %	0.04 [-0.19, 0.26]
Paatelma 2008 (38)	23	0 (1.5)	52	1 (1.5)		3.4 %	-0.66 [-1.16, -0.16]
Paatelma 2008 (39)	23	0 (1.5)	37	0 (2.2)		3.1 %	0.0 [-0.52, 0.52]
(39) vs. advice							

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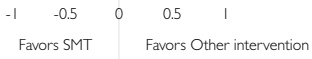
Study or subgroup	SMT N	SMT Mean(SD)	Other intervention N	Other intervention Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
Rasmussen-Barr 2003	14	8 (9.6)	17	8 (5.9)		1.7 %	0.0 [-0.71, 0.71]
UK BEAM trial 2004	273	5.15 (4.79)	216	5.74 (4.56)		26.6 %	-0.13 [-0.30, 0.05]
Zaproudina 2009	50	12.5 (11)	53	16 (10.7)		5.6 %	-0.32 [-0.71, 0.07]
Subtotal (95% CI)	**904**		**956**			**100.0 %**	**-0.09 [-0.18, 0.00]**

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 9.21$, df = 10 (P = 0.51); $I^2 = 0.0\%$

Test for overall effect: Z = 1.93 (P = 0.053)



(1) HVLA-SMT + strength exercises vs. NSAID + strength exercises; RMDQ

(2) SMT (flexion-distraction) vs. exercise; RMDQ; ITT data; change scores presented - used SD from baseline

(3) SMT vs. exercise; change scores presented; SD's used from baseline; number of SMT subjects was halved; Oswestry.

(4) SMT vs. physiotherapy; change scores presented in text; SD's used from baseline; number of SMT subjects was halved; Oswestry.

(5) LVVA-SMT (flexion-distraction) vs. medical care; RMDQ; adjusted scores from linear effects model - data from author

(6) HVLA-SMT vs medical care; RMDQ; adjusted scores from linear effects model - data from author

(7) HVLA-SMT vs. back school; RMDQ

(8) HVLA-SMT vs. Myofascial therapy; RMDQ

(9) chiropractic care + physical modalities vs. medical care + physical therapy; data from 6 weeks; RMDQ; data estimated from graphs; SD used from baseline score

(10) chiropractic care only vs. medical care only; data from 6 weeks; RMDQ; data estimated from graphs; SD used from baseline score

(11) SMT (Maitland) + exercise vs. ultrasound + exercise; Oswestry

(12) Manual therapy vs. stabilization training; median (IQR) converted to mean (SD); Oswestry

(13) Naprapathy vs. std. medical care; data provided by author; chronic pain questionnaire (CPQ) - von Korff scale;

(14) "chiropractic management" vs. outpatient hospital pain clinic; RMDQ

(15) SMT vs. general + motor control exercise; RMDQ

(16) vs. physiotherapy

(17) vs. exercise

(18) HVLA SMT

(19) Flexion-distraction

(20) vs. McKenzie

(21) vs. advice group

(22) Best care + SMT vs. Best care + exercise; RMDQ

(23) Bone-setting vs. physiotherapy; Oswestry; post.tx = ~3 months post-baseline; data provided by author

(24) vs. physiotherapy

(25) vs. exercise

(26) HVLA SMT

(27) Flexion-distraction

(28) vs. back school

(29) vs. myofascial therapy

(30) MD care only

(31) + physiotherapy modalities

(32) vs. advice

(33) vs. McKenzie

(34) vs. exercise

(35) vs. physiotherapy

(39) vs. advice

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Study or subgroup	SMT N	SMT Mean(SD)	Other intervention N	Other intervention Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
(36) vs. MD care only							
(37) + physiotherapy modalities							
(38) vs. McKenzie							
(39) vs. advice							

Analysis 3.3. Comparison 3 SMT vs. any other intervention, Outcome 3 Perceived recovery.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 3 SMT vs. any other intervention

Outcome: 3 Perceived recovery

Study or subgroup	SMT n/N	Other intervention n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Recovery at 1 month					
Gibson 1985 (1)	11/39	9/32		3.4 %	1.00 [0.48, 2.12]
Gudavalli 2006 (2)	82/103	54/83		54.4 %	1.22 [1.02, 1.47]
Hemmila 2002 (3)	18/22	26/34		25.5 %	1.07 [0.82, 1.40]
Hemmila 2002 (4)	18/22	21/35		16.7 %	1.36 [0.98, 1.91]
Subtotal (95% CI)	**186**	**184**		**100.0 %**	**1.20 [1.04, 1.37]**
Total events: 129 (SMT), 110 (Other intervention)					
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 1.51$, df = 3 (P = 0.68); $I^2 = 0.0\%$					
Test for overall effect: Z = 2.56 (P = 0.010)					
2 Recovery at 3 months					
Gibson 1985	16/38	8/27		24.9 %	1.42 [0.71, 2.83]
Zaproudina 2009 (5)	36/57	21/60		75.1 %	1.80 [1.21, 2.69]
Subtotal (95% CI)	**95**	**87**		**100.0 %**	**1.70 [1.20, 2.40]**
Total events: 52 (SMT), 29 (Other intervention)					
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.35$, df = 1 (P = 0.56); $I^2 = 0.0\%$					
Test for overall effect: Z = 3.02 (P = 0.0025)					
3 Recovery at 6 months					
Hemmila 2002 (6)	15/22	22/34		50.0 %	1.05 [0.72, 1.54]
Hemmila 2002 (7)	15/22	22/34		50.0 %	1.05 [0.72, 1.54]
Subtotal (95% CI)	**44**	**68**		**100.0 %**	**1.05 [0.81, 1.38]**
(9) vs. physiotherapy					

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Study or subgroup	SMT n/N	Other intervention n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Total events: 30 (SMT), 44 (Other intervention)					
Heterogeneity: Tau² = 0.0; Chi² = 0.0, df = 1 (P = 1.00); I² =0.0%					
Test for overall effect: Z = 0.38 (P = 0.70)					
4 Recovery at 12 months					
Hemmila 2002 (8)	15/22	18/32		47.3 %	1.21 [0.80, 1.84]
Hemmila 2002 (9)	15/22	20/33		52.7 %	1.13 [0.76, 1.67]
Subtotal (95% CI)	**44**	**65**		**100.0 %**	**1.17 [0.87, 1.55]**
Total events: 30 (SMT), 38 (Other intervention)					
Heterogeneity: Tau² = 0.0; Chi² = 0.06, df = 1 (P = 0.80); I² =0.0%					
Test for overall effect: Z = 1.04 (P = 0.30)					

(1) SMT vs. short-wave diathermy (SWD); number of patients free of pain

(2) Question posed to patients, "Overall, how much were you helped?"; answers were dichotomized by "quite a bit" % "very much" to "a little bit", "not at all" % "not sure".

(3) SMT vs. physiotherapy; no. of patients improved

(4) SMT vs. exercise

(5) Bone-setting vs. physiotherapy; Global assessment on 11-point scale - dichotomized into <8 vs. >=8; post-tx. =~3 mos. post-baseline

(6) vs. exercise

(7) vs. physiotherapy

(8) vs. exercise

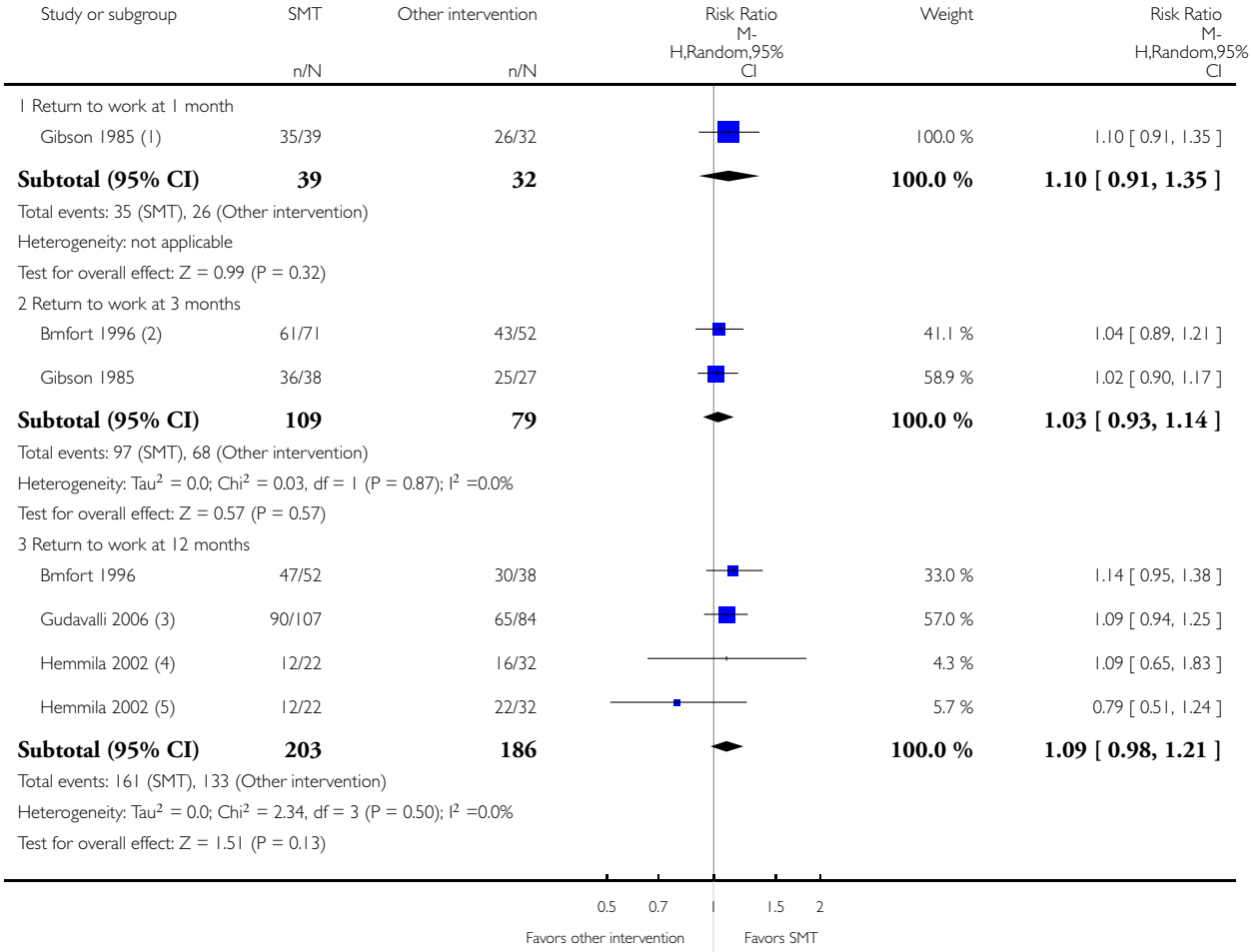
(9) vs. physiotherapy

Analysis 3.4. Comparison 3 SMT vs. any other intervention, Outcome 4 Return to work.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 3 SMT vs. any other intervention

Outcome: 4 Return to work



(1) osteopathic SMT vs. short-wave diathermy (SWD); no. able to work or with unrestricted activities

(2) chiropractic SMT vs. NSAIDs; no. who returned to work at full or reduced capacity.

(3) SMT (flexion-distraction) vs. exercise; no. that did not take sick-leave due to LBP

(4) SMT vs. exercise; no. not sick-listed the year after therapy

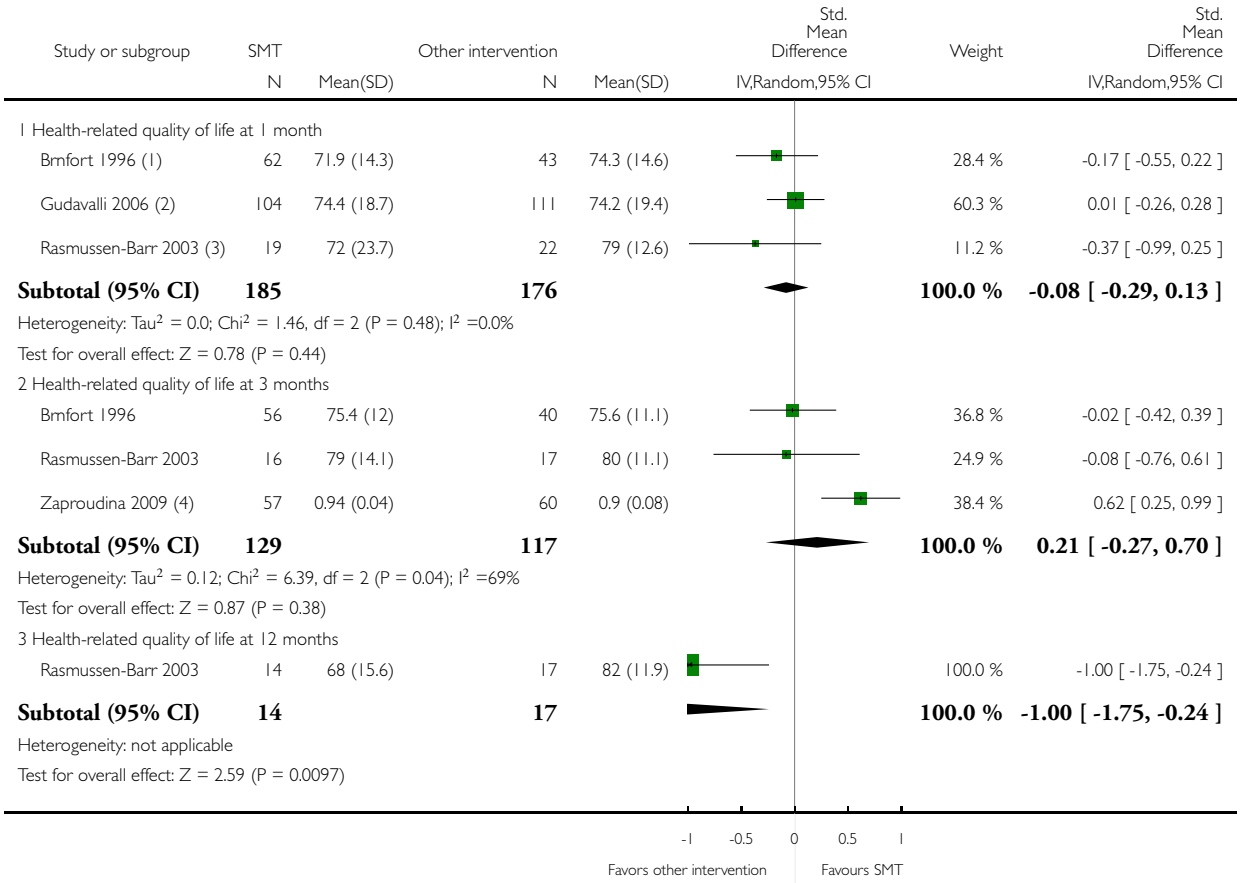
(5) SMT vs. physiotherapy; no. not sick-listed the year after therapy

Analysis 3.5. Comparison 3 SMT vs. any other intervention, Outcome 5 Health-related Quality of Life.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 3 SMT vs. any other intervention

Outcome: 5 Health-related Quality of Life



(1) chiropractic SMT + exercise vs. NSAIDs + exercise; Global General Health Status (as measured by COOP Chart scores); 0-100 where 100 = optimal health

(2) Mobilization (flexion-distraction) vs. exercise therapy; SF-36 (general health subscale); change scores presented; SD from baseline used; per-protocol data - only available

(3) Manual therapy vs. stabilization training; General health - 10 cm VAS - Best to worst health - but converted here; median (IQR) converted to mean (SD)

(4) Bone-setting vs. physio; HRQoL (15D) = Health-related Quality of Life: range=0-1, where 1=healthy population; 1 mos. post-tx. = ~3 mos. post-baseline

Analysis 4.1. Comparison 4 Subset of comparison 3. SMT vs. ineffective interventions, Outcome 1 Pain.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 4 Subset of comparison 3. SMT vs. ineffective interventions

Outcome: 1 Pain

Study or subgroup	SMT N	Mean(SD)	Passive/ineff intervent. N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Pain at 1 month							
Gibson 1985 (1)	39	21 (22.5)	32	28 (24)		26.8 %	-7.00 [-17.91, 3.91]
Hsieh 2002 (2)	45	25.8 (19.3)	49	27.8 (18.2)		35.7 %	-2.00 [-9.60, 5.60]
Mohseni-Bandpei 2006 (3)	56	23.4 (19)	56	37.9 (19)		37.4 %	-14.50 [-21.54, -7.46]
Subtotal (95% CI)	**140**		**137**			**100.0 %**	**-8.02 [-16.14, 0.10]**
Heterogeneity: Tau^2 = 33.02; Chi^2 = 5.67, df = 2 (P = 0.06); I^2 =65%							
Test for overall effect: Z = 1.93 (P = 0.053)							
2 Pain at 3 months							
Gibson 1985	38	13 (22.5)	27	25 (22.5)		43.0 %	-12.00 [-23.10, -0.90]
Paatelma 2008 (4)	45	18 (12.6)	37	17 (13.3)		57.0 %	1.00 [-4.65, 6.65]
Subtotal (95% CI)	**83**		**64**			**100.0 %**	**-4.59 [-17.20, 8.03]**
Heterogeneity: Tau^2 = 64.31; Chi^2 = 4.19, df = 1 (P = 0.04); I^2 =76%							
Test for overall effect: Z = 0.71 (P = 0.48)							
3 Pain at 6 months							
Hsieh 2002	40	24 (24.1)	47	29.9 (22.8)		20.7 %	-5.90 [-15.81, 4.01]
Mohseni-Bandpei 2006	40	27.1 (19)	33	40.2 (19)		26.5 %	-13.10 [-21.86, -4.34]
Paatelma 2008	45	14 (8.1)	37	22 (17.8)		52.8 %	-8.00 [-14.20, -1.80]
Subtotal (95% CI)	**125**		**117**			**100.0 %**	**-8.92 [-13.43, -4.41]**
Heterogeneity: Tau^2 = 0.0; Chi^2 = 1.32, df = 2 (P = 0.52); I^2 =0.0%							
Test for overall effect: Z = 3.88 (P = 0.00011)							
4 Pain at 12 months							
Paatelma 2008	45	11 (14.1)	37	16 (19.3)		100.0 %	-5.00 [-12.46, 2.46]
Subtotal (95% CI)	**45**		**37**			**100.0 %**	**-5.00 [-12.46, 2.46]**
Heterogeneity: not applicable							
Test for overall effect: Z = 1.31 (P = 0.19)							

(1) osteopathic SMT vs. diathermy; median (range) presented in text - and converted; daytime pain

(2) chiropractic SMT vs. Myofascial therapy

(3) manual therapy SMT + exercise vs. Ultrasound + exercise

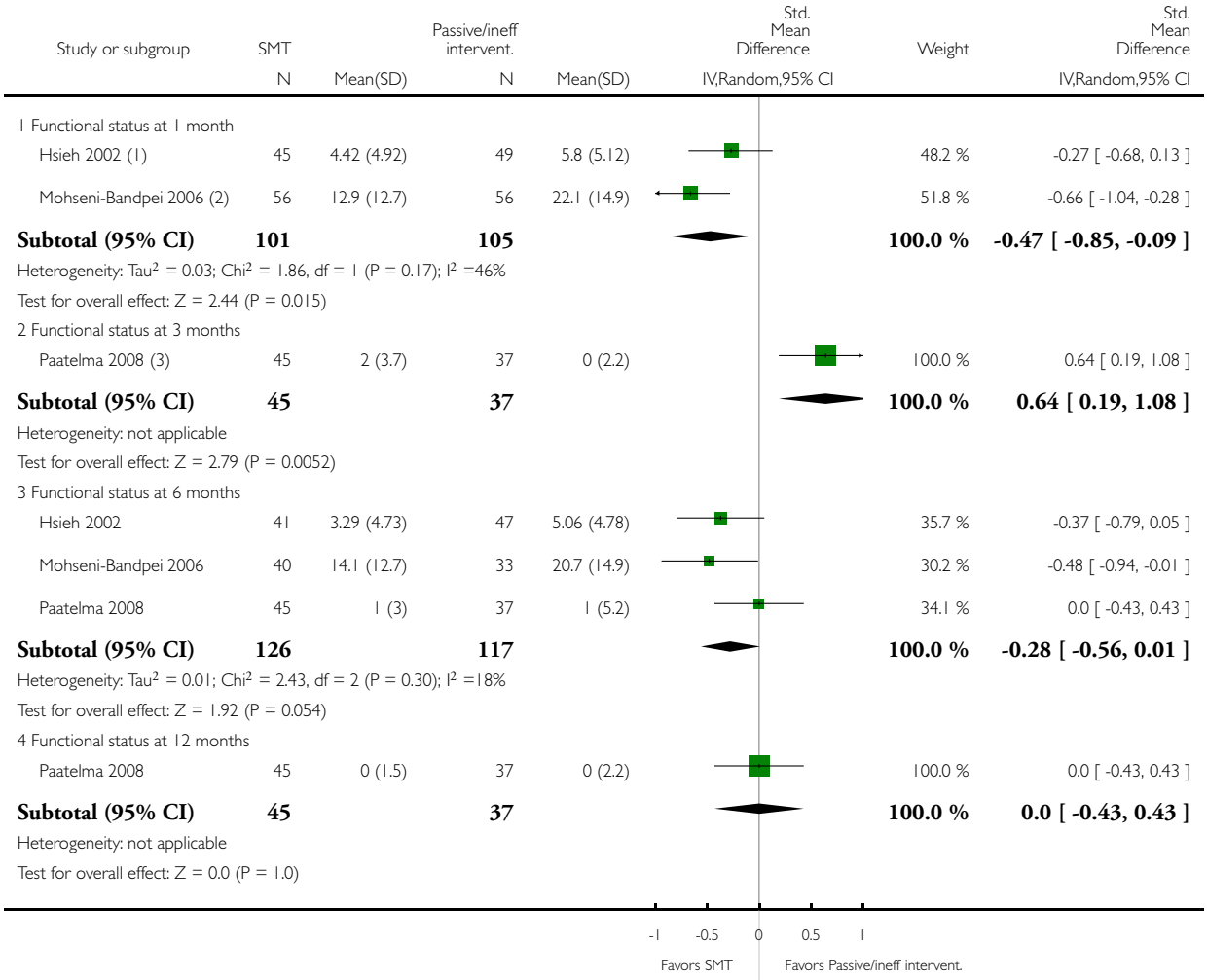
(4) OMT vs. Advice-group (counseling session + educational back booklet)

Analysis 4.2. Comparison 4 Subset of comparison 3. SMT vs. ineffective interventions, Outcome 2 Functional status.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 4 Subset of comparison 3. SMT vs. ineffective interventions

Outcome: 2 Functional status



(1) HVLA-SMT vs. Myofascial therapy; RMDQ

(2) SMT (Maitland) + exercise vs. ultrasound + exercise; Oswestry

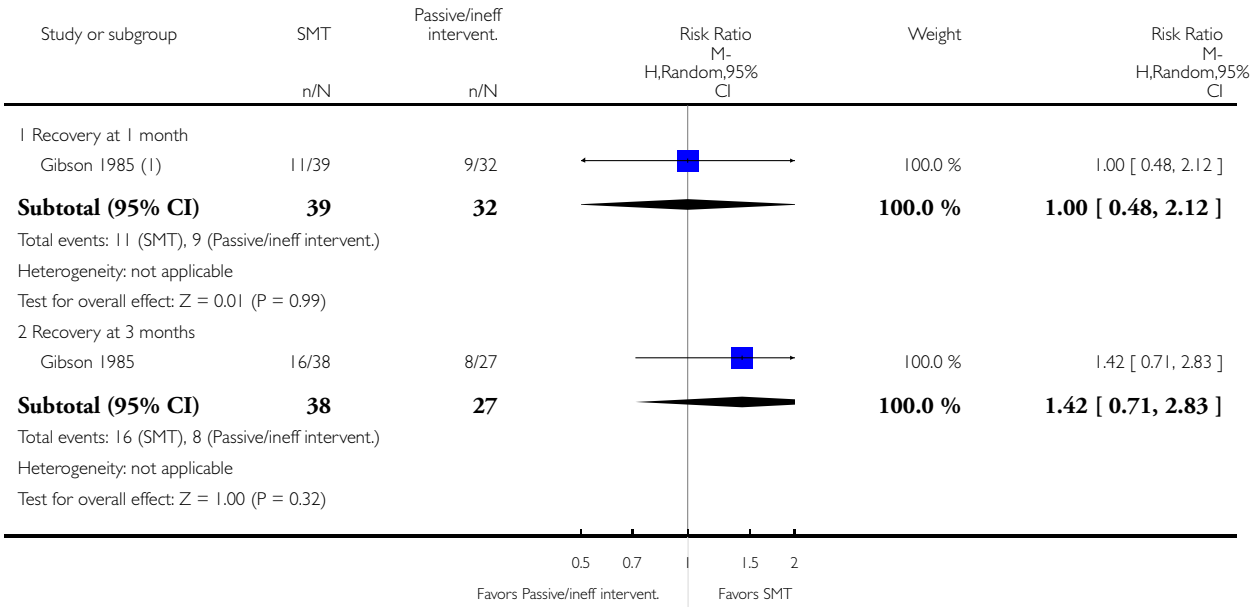
(3) OMT vs. advice group; RMDQ; median (IQR) converted to mean (SD).

Analysis 4.3. Comparison 4 Subset of comparison 3. SMT vs. ineffective interventions, Outcome 3 Perceived recovery.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 4 Subset of comparison 3. SMT vs. ineffective interventions

Outcome: 3 Perceived recovery



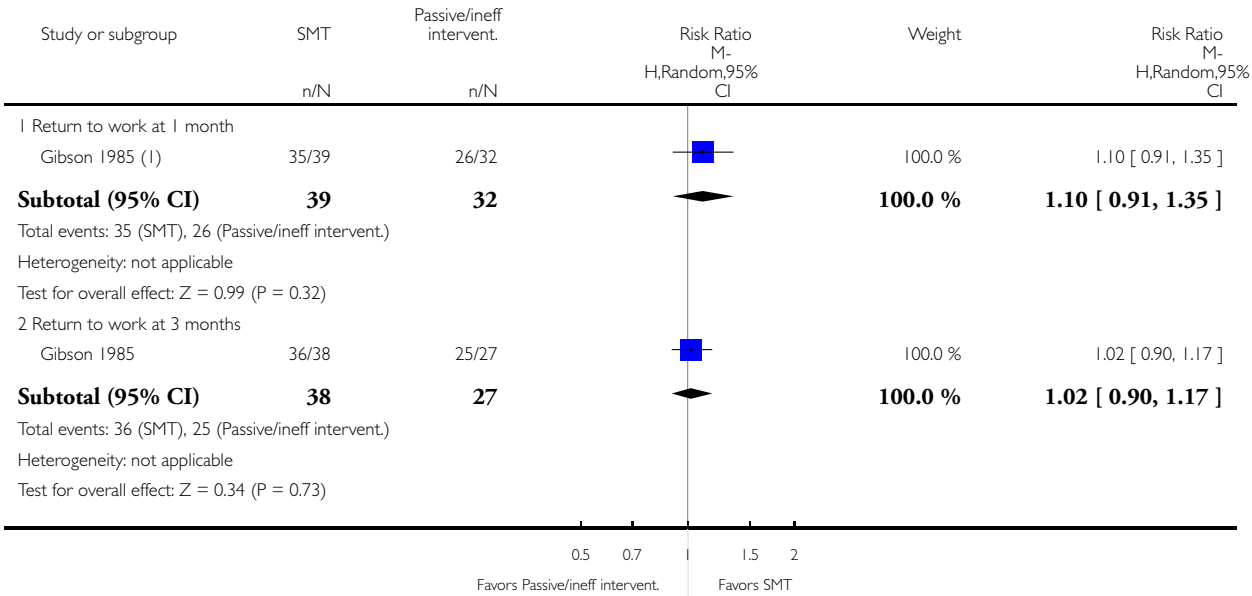
(1) SMT vs. short-wave diathermy (SWD); no. of patients free of pain

Analysis 4.4. Comparison 4 Subset of comparison 3. SMT vs. ineffective interventions, Outcome 4 Return to work.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 4 Subset of comparison 3. SMT vs. ineffective interventions

Outcome: 4 Return to work



(1) SMT vs. short-wave diathermy (SWD); no. able to work or with unrestricted activities

Analysis 5.1. Comparison 5 Subset of comparison 3. SMT vs. effective interventions, Outcome 1 Pain.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 5 Subset of comparison 3. SMT vs. effective interventions

Outcome: 1 Pain

Study or subgroup	SMT N	Mean(SD)	Active/Eff. intervention N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Pain at 1 month							
Brnfort 1996 (1)	62	34 (19)	43	36 (22)		7.6 %	-2.00 [-10.10, 6.10]
Gudavalli 2006 (2)	123	17.4 (22.3)	112	23.4 (20.7)		11.0 %	-6.00 [-11.50, -0.50]
Hemmila 2002 (3)	22	30.5 (15)	35	30 (15)		7.7 %	0.50 [-7.50, 8.50]
Hemmila 2002 (4)	22	30.5 (15)	34	27 (15)		7.6 %	3.50 [-4.54, 11.54]
Hondras 2009 (5)	83	27.63 (19.31)	16	33.47 (19.49)		5.5 %	-5.84 [-16.25, 4.57]
Hondras 2009 (6)	90	29.49 (19.29)	16	33.47 (19.49)		5.6 %	-3.98 [-14.33, 6.37]
Hsieh 2002 (7)	45	25.8 (19.3)	42	21.3 (12.8)		9.1 %	4.50 [-2.34, 11.34]
Hurwitz 2002 (8)	169	31 (18)	168	35 (20)		13.3 %	-4.00 [-8.06, 0.06]
Hurwitz 2002 (9)	169	34 (19)	169	36 (19)		13.4 %	-2.00 [-6.05, 2.05]
Rasmussen-Barr 2003 (10)	19	24 (26.7)	22	20 (17.8)		3.5 %	4.00 [-10.12, 18.12]
Skillgate 2007 (11)	92	36 (14.4)	80	44 (13.4)		13.2 %	-8.00 [-12.16, -3.84]
Wilkey 2008 (12)	18	42.8 (22.5)	12	70 (24.1)		2.5 %	-27.20 [-44.35, -10.05]
Subtotal (95% CI)	**914**		**749**			**100.0 %**	**-3.04 [-5.98, -0.10]**
Heterogeneity: Tau^2 = 12.58; Chi^2 = 23.76, df = 11 (P = 0.01); I^2 =54%							
Test for overall effect: Z = 2.03 (P = 0.043)							
2 Pain at 3 months							
Brnfort 1996	56	27 (20)	40	35 (22)		9.0 %	-8.00 [-16.60, 0.60]
Ferreira 2007 (13)	77	41 (26)	147	44 (24.5)		10.3 %	-3.00 [-10.03, 4.03]
Gudavalli 2006	87	21.5 (22.3)	76	23.7 (20.7)		10.7 %	-2.20 [-8.80, 4.40]
Hemmila 2002 (14)	22	30 (15)	34	27.5 (15)		9.5 %	2.50 [-5.54, 10.54]
Hemmila 2002 (15)	22	30 (15)	35	31 (15)		9.5 %	-1.00 [-9.00, 7.00]
Paatelma 2008 (16)	45	18 (12.6)	52	10 (14.8)		11.7 %	8.00 [2.55, 13.45]
Rasmussen-Barr 2003	16	22 (28.1)	17	14 (14.1)		5.0 %	8.00 [-7.31, 23.31]
Skillgate 2007	89	26 (14.4)	73	37 (13.4)		12.6 %	-11.00 [-15.29, -6.71]
UK BEAM trial 2004 (17)	275	40.9 (24.87)	204	44.73 (24.42)		12.5 %	-3.83 [-8.29, 0.63]
Zaproudina 2009 (18)	57	23.4 (23.9)	60	28 (20.9)		9.4 %	-4.60 [-12.75, 3.55]
Subtotal (95% CI)	**746**		**738**			**100.0 %**	**-2.09 [-6.29, 2.11]**
(27) vs. McKenzie							

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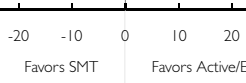
Study or subgroup	SMT N	Mean(SD)	Active/Eff. interven-tion N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
Heterogeneity: Tau² = 31.65; Chi² = 34.65, df = 9 (P = 0.00007); I² =74%							
Test for overall effect: Z = 0.98 (P = 0.33)							
3 Pain at 6 months							
Ferreira 2007	72	43 (26)	139	45.6 (26)		9.4 %	-2.60 [-10.00, 4.80]
Gudavalli 2006	90	19.7 (22.3)	74	26.8 (20.7)		10.7 %	-7.10 [-13.69, -0.51]
Hemmila 2002 (19)	22	25 (15)	35	30 (15)		8.6 %	-5.00 [-13.00, 3.00]
Hemmila 2002 (20)	22	25 (15)	34	26 (15)		8.5 %	-1.00 [-9.04, 7.04]
Hsieh 2002 (21)	40	24 (24.1)	42	22.9 (19.8)		6.8 %	1.10 [-8.47, 10.67]
Hurwitz 2002 (22)	163	18 (18)	159	22 (20)		15.4 %	-4.00 [-8.16, 0.16]
Hurwitz 2002 (23)	165	26 (19)	165	28.5 (19)		15.5 %	-2.50 [-6.60, 1.60]
Paatelma 2008 (24)	45	14 (8.1)	52	10 (7.4)		17.7 %	4.00 [0.89, 7.11]
Zaproudina 2009	57	24.5 (24.6)	60	31.3 (25.6)		7.3 %	-6.80 [-15.90, 2.30]
Subtotal (95% CI)	**676**		**760**			**100.0 %**	**-2.24 [-5.25, 0.78]**
Heterogeneity: Tau² = 10.84; Chi² = 18.64, df = 8 (P = 0.02); I² =57%							
Test for overall effect: Z = 1.45 (P = 0.15)							
4 Pain at 12 months							
Ferreira 2007	73	49 (27)	138	50.6 (28.5)		6.9 %	-1.60 [-9.41, 6.21]
Gudavalli 2006	96	20.9 (22.3)	78	23.3 (20.7)		10.3 %	-2.40 [-8.80, 4.00]
Hurwitz 2002 (25)	156	27.5 (18)	148	28 (20)		22.9 %	-0.50 [-4.78, 3.78]
Hurwitz 2002 (26)	153	32.5 (19)	153	34 (19)		23.2 %	-1.50 [-5.76, 2.76]
Paatelma 2008 (27)	45	11 (14.1)	52	8 (17)		11.0 %	3.00 [-3.19, 9.19]
Rasmussen-Barr 2003	14	18 (21.5)	17	13 (13.3)		2.5 %	5.00 [-7.92, 17.92]
UK BEAM trial 2004	264	41.68 (25.67)	200	41.54 (26.02)		18.6 %	0.14 [-4.61, 4.89]
Zaproudina 2009	50	26.6 (26.2)	53	30.7 (23.9)		4.5 %	-4.10 [-13.80, 5.60]
Subtotal (95% CI)	**851**		**839**			**100.0 %**	**-0.52 [-2.57, 1.53]**
Heterogeneity: Tau² = 0.0; Chi² = 3.15, df = 7 (P = 0.87); I² =0.0%							
Test for overall effect: Z = 0.50 (P = 0.62)							



(1) HVLA-SMT + strength exercises vs. NSAID + strength exercises;

(2) SMT (flexion-distraction) vs. exercise; ITT data; change scores presented - used SD from baseline

(3) vs. exercise

(4) vs. FT

(5) LVVA-SMT (flexion-distraction) vs. medical care; adjusted scores from linear effects model; data from author

(6) HVLA-SMT vs medical care; adjusted scores from linear effects model; data from author

(7) SMT vs. Back school

(8) chiropractic care +physical modalities (DCPm) vs. medical care + physical therapy (MDpt); data from 6 weeks; average pain; data estimated from graphs; SD used from baseline

(27) vs. McKenzie

(*Continued* . . .)

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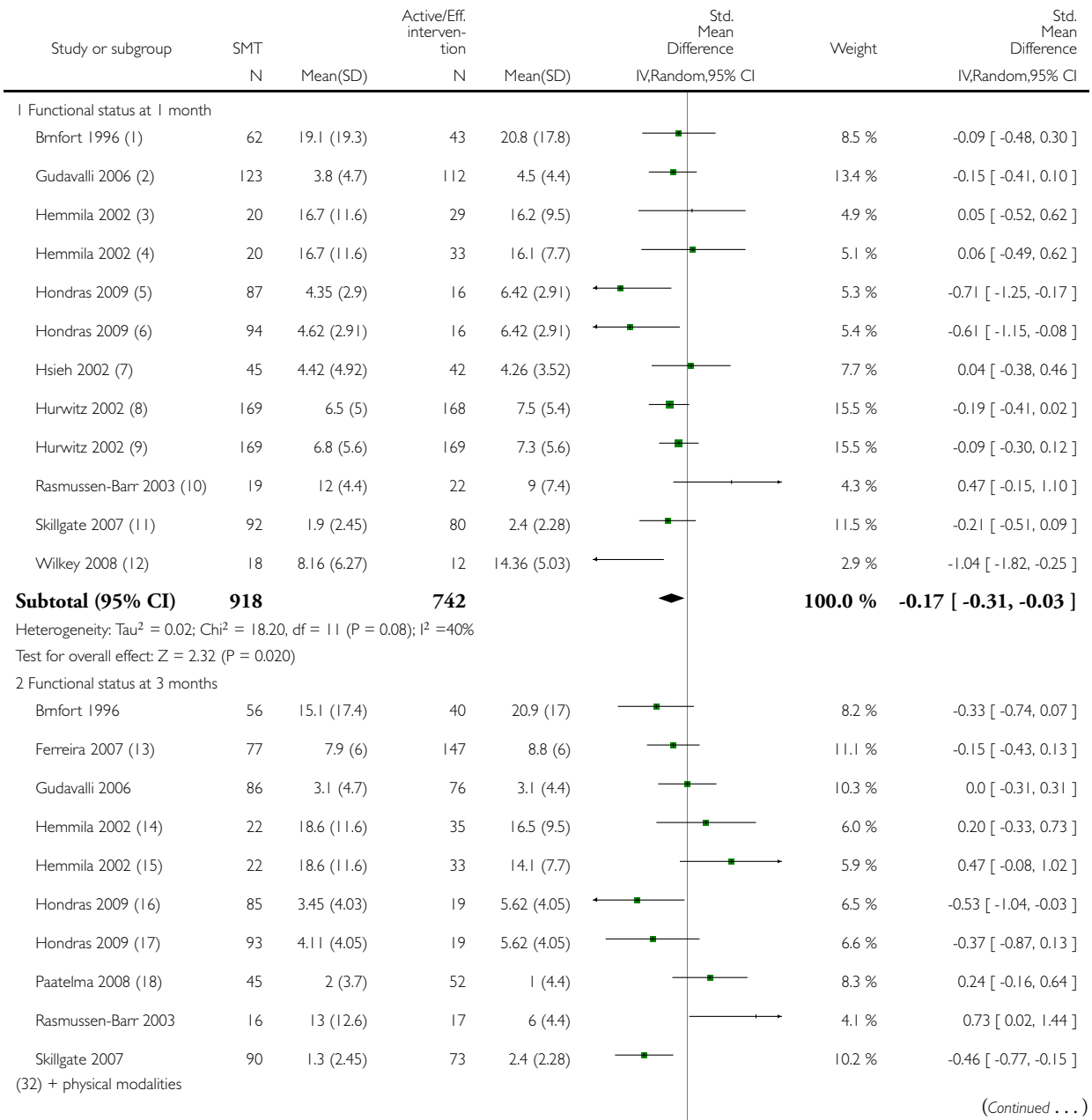
Study or subgroup	SMT		Active/Eff. interven-tion		Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	IV,Random,95% CI		IV,Random,95% CI
(9) chiropractic care only vs. medical care only; data from 6 weeks; average pain; data estimated from graphs; SD used from baseline							
(10) Manual therapy vs. stabilizing training							
(11) Naprapathy vs. std. medical care; data provided by author							
(12) "chiropractic management" vs. outpatient hospital pain clinic							
(13) vs. motor control + general exercise (combined)							
(14) vs. physiotherapy							
(15) vs. exercise							
(16) OMT vs. McKenzie; VAS; median (IQR) - converted to mean (SD)							
(17) Best care + SMT vs. Best care + exercise; Modified von Korff - pain subscale only							
(18) Bone-setting vs. physiotherapy; VAS; data provided by primary author; one month post-tx. = 3 months							
(19) vs. exercise							
(20) vs. physiotherapy							
(21) vs. back school							
(22) +physical modalities (DCPm)							
(23) vs. medical care only							
(24) vs McKenzie							
(25) +physical modalities (DCPm)							
(26) vs. medical care only							
(27) vs. McKenzie							

Analysis 5.2. Comparison 5 Subset of comparison 3. SMT vs. effective interventions, Outcome 2 Functional status.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 5 Subset of comparison 3. SMT vs. effective interventions

Outcome: 2 Functional status



Study or subgroup	SMT N	Mean(SD)	Active/Eff. intervention N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
1 Functional status at 1 month							
Brnfort 1996 (1)	62	19.1 (19.3)	43	20.8 (17.8)		8.5 %	-0.09 [-0.48, 0.30]
Gudavalli 2006 (2)	123	3.8 (4.7)	112	4.5 (4.4)		13.4 %	-0.15 [-0.41, 0.10]
Hemmila 2002 (3)	20	16.7 (11.6)	29	16.2 (9.5)		4.9 %	0.05 [-0.52, 0.62]
Hemmila 2002 (4)	20	16.7 (11.6)	33	16.1 (7.7)		5.1 %	0.06 [-0.49, 0.62]
Hondras 2009 (5)	87	4.35 (2.9)	16	6.42 (2.91)		5.3 %	-0.71 [-1.25, -0.17]
Hondras 2009 (6)	94	4.62 (2.91)	16	6.42 (2.91)		5.4 %	-0.61 [-1.15, -0.08]
Hsieh 2002 (7)	45	4.42 (4.92)	42	4.26 (3.52)		7.7 %	0.04 [-0.38, 0.46]
Hurwitz 2002 (8)	169	6.5 (5)	168	7.5 (5.4)		15.5 %	-0.19 [-0.41, 0.02]
Hurwitz 2002 (9)	169	6.8 (5.6)	169	7.3 (5.6)		15.5 %	-0.09 [-0.30, 0.12]
Rasmussen-Barr 2003 (10)	19	12 (4.4)	22	9 (7.4)		4.3 %	0.47 [-0.15, 1.10]
Skillgate 2007 (11)	92	1.9 (2.45)	80	2.4 (2.28)		11.5 %	-0.21 [-0.51, 0.09]
Wilkey 2008 (12)	18	8.16 (6.27)	12	14.36 (5.03)		2.9 %	-1.04 [-1.82, -0.25]
Subtotal (95% CI)	**918**		**742**			**100.0 %**	**-0.17 [-0.31, -0.03]**
Heterogeneity: Tau² = 0.02; Chi² = 18.20, df = 11 (P = 0.08); I² =40%							
Test for overall effect: Z = 2.32 (P = 0.020)							
2 Functional status at 3 months							
Brnfort 1996	56	15.1 (17.4)	40	20.9 (17)		8.2 %	-0.33 [-0.74, 0.07]
Ferreira 2007 (13)	77	7.9 (6)	147	8.8 (6)		11.1 %	-0.15 [-0.43, 0.13]
Gudavalli 2006	86	3.1 (4.7)	76	3.1 (4.4)		10.3 %	0.0 [-0.31, 0.31]
Hemmila 2002 (14)	22	18.6 (11.6)	35	16.5 (9.5)		6.0 %	0.20 [-0.33, 0.73]
Hemmila 2002 (15)	22	18.6 (11.6)	33	14.1 (7.7)		5.9 %	0.47 [-0.08, 1.02]
Hondras 2009 (16)	85	3.45 (4.03)	19	5.62 (4.05)		6.5 %	-0.53 [-1.04, -0.03]
Hondras 2009 (17)	93	4.11 (4.05)	19	5.62 (4.05)		6.6 %	-0.37 [-0.87, 0.13]
Paatelma 2008 (18)	45	2 (3.7)	52	1 (4.4)		8.3 %	0.24 [-0.16, 0.64]
Rasmussen-Barr 2003	16	13 (12.6)	17	6 (4.4)		4.1 %	0.73 [0.02, 1.44]
Skillgate 2007	90	1.3 (2.45)	73	2.4 (2.28)		10.2 %	-0.46 [-0.77, -0.15]
(32) + physical modalities							

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Study or subgroup	SMT N	SMT Mean(SD)	Active/Eff. interven-tion N	Active/Eff. interven-tion Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
UK BEAM trial 2004 (19)	287	5.09 (4.74)	225	5.47 (4.35)		13.6 %	-0.08 [-0.26, 0.09]
Zaproudina 2009 (20)	57	12.2 (10.9)	60	15.9 (10.1)		9.0 %	-0.35 [-0.72, 0.02]
Subtotal (95% CI)	**936**		**796**			**100.0 %**	**-0.10 [-0.27, 0.06]**
Heterogeneity: Tau² = 0.05; Chi² = 26.08, df = 11 (P = 0.01); I² =58%							
Test for overall effect: Z = 1.22 (P = 0.22)							
3 Functional status at 6 months							
Ferreira 2007	72	7.7 (6.2)	139	9.3 (6.7)		12.5 %	-0.24 [-0.53, 0.04]
Gudavalli 2006	90	2.8 (4.7)	78	3.4 (4.4)		11.1 %	-0.13 [-0.43, 0.17]
Hemmila 2002 (21)	22	14.3 (11.6)	33	13.4 (7.7)		3.7 %	0.09 [-0.45, 0.63]
Hemmila 2002 (22)	22	14.3 (11.6)	33	15.9 (9.5)		3.6 %	-0.15 [-0.69, 0.39]
Hondras 2009 (23)	86	3.44 (4.39)	17	5.34 (4.27)		3.9 %	-0.43 [-0.96, 0.09]
Hondras 2009 (24)	89	4.06 (4.36)	17	5.34 (4.27)		3.9 %	-0.29 [-0.81, 0.23]
Hsieh 2002 (25)	41	3.29 (4.73)	42	3.48 (3.86)		5.7 %	-0.04 [-0.47, 0.39]
Hurwitz 2002 (26)	163	3.8 (5)	159	3.5 (5.4)		20.4 %	0.06 [-0.16, 0.28]
Hurwitz 2002 (27)	165	4.1 (5.6)	165	4.8 (5.6)		20.8 %	-0.12 [-0.34, 0.09]
Paatelma 2008 (28)	45	1 (3)	52	0 (3)		6.5 %	0.33 [-0.07, 0.73]
Zaproudina 2009	57	12.2 (12.1)	60	14.5 (8.9)		7.9 %	-0.22 [-0.58, 0.15]
Subtotal (95% CI)	**852**		**795**			**100.0 %**	**-0.09 [-0.19, 0.02]**
Heterogeneity: Tau² = 0.00; Chi² = 10.46, df = 10 (P = 0.40); I² =4%							
Test for overall effect: Z = 1.65 (P = 0.099)							
4 Functional status at 12 months							
Ferreira 2007	73	9.2 (6.6)	138	9.2 (6.7)		11.7 %	0.0 [-0.28, 0.28]
Gudavalli 2006	95	2.7 (4.7)	78	3.1 (4.4)		10.7 %	-0.09 [-0.39, 0.21]
Hemmila 2002 (29)	22	15.3 (11.6)	32	17.2 (9.5)		3.9 %	-0.18 [-0.72, 0.36]
Hemmila 2002 (30)	22	15.3 (11.6)	32	13.7 (7.7)		3.9 %	0.17 [-0.38, 0.71]
Hurwitz 2002 (31)	153	6.6 (5.6)	153	7.1 (5.6)		16.3 %	-0.09 [-0.31, 0.14]
Hurwitz 2002 (32)	156	6.2 (5)	148	6 (5.4)		16.2 %	0.04 [-0.19, 0.26]
Paatelma 2008	45	0 (1.5)	52	1 (1.5)		6.4 %	-0.66 [-1.07, -0.25]
Rasmussen-Barr 2003	14	8 (9.6)	17	8 (5.9)		2.4 %	0.0 [-0.71, 0.71]
UK BEAM trial 2004	273	5.15 (4.79)	216	5.74 (4.56)		21.5 %	-0.13 [-0.30, 0.05]
Zaproudina 2009	50	12.5 (11)	53	16 (10.7)		7.0 %	-0.32 [-0.71, 0.07]
Subtotal (95% CI)	**903**		**919**			**100.0 %**	**-0.11 [-0.22, 0.00]**
Heterogeneity: Tau² = 0.01; Chi² = 11.53, df = 9 (P = 0.24); I² =22%							
Test for overall effect: Z = 1.93 (P = 0.053)							
(32) + physical modalities							

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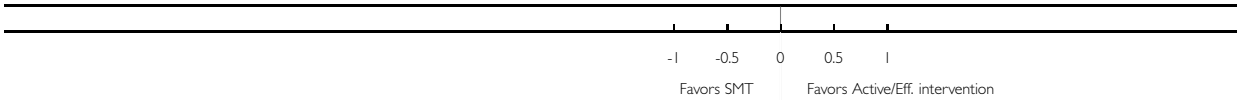
Study or subgroup	SMT		Active/Eff. interven-tion		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	IV,Random,95% CI		IV,Random,95% CI



(1) HVLA-SMT + strength exercises vs. NSAID + strength exercises; RMDQ

(2) SMT (flexion-distraction) vs. exercise; RMDQ; ITT data; change scores presented - used SD from baseline

(3) SMT vs. exercise; change scores presented; SD's used from baseline; number of SMT subjects was halved; Oswestry.

(4) SMT vs. physiotherapy; change scores presented in text; SD's used from baseline; number of SMT subjects was halved; Oswestry.

(5) LVVA-SMT (flexion-distraction) vs. medical care; RMDQ; adjusted scores from linear effects model - data from author

(6) HVLA-SMT vs medical care; RMDQ; adjusted scores from linear effects model - data from author

(7) HVLA-SMT vs. back school; RMDQ

(8) chiropractic care + physical modalities vs. medical care + physical therapy; data from 6 weeks; RMDQ; data estimated from graphs; SD used from baseline

(9) chiropractic care only vs. medical care only; data from 6 weeks; RMDQ; data estimated from graphs; SD used from baseline score

(10) Manual therapy vs. stabilization training; median (IQR) converted to mean (SD); Oswestry

(11) Naprapathy vs. std. medical care; data provided by author; CPQ - von Korff scale

(12) "chiropractic management" vs. outpatient hospital pain clinic; RMDQ

(13) SMT vs. general + motor control exercise; RMDQ

(14) vs. exercise

(15) vs. physiotherapy

(16) LVVA-SMT (flexion-distraction) vs. medical care

(17) HVLA-SMT vs medical care

(18) OMT vs. McKenzie; RMDQ; median (IQR) converted to mean (SD).

(19) Best care + SMT vs. Best care + exercise; RMDQ

(20) Bone-setting vs. physiotherapy; Oswestry; post.tx = ~3 months post-baseline; data provided by author

(21) vs. physiotherapy

(22) vs. exercise

(23) LVVA-SMT (flexion-distraction) vs. medical care

(24) HVLA-SMT vs medical care

(25) vs. back school

(26) + physical modalities

(27) vs. medical care only

(28) vs. McKenzie

(29) vs. exercise

(30) vs. physiotherapy

(31) vs. medical care only

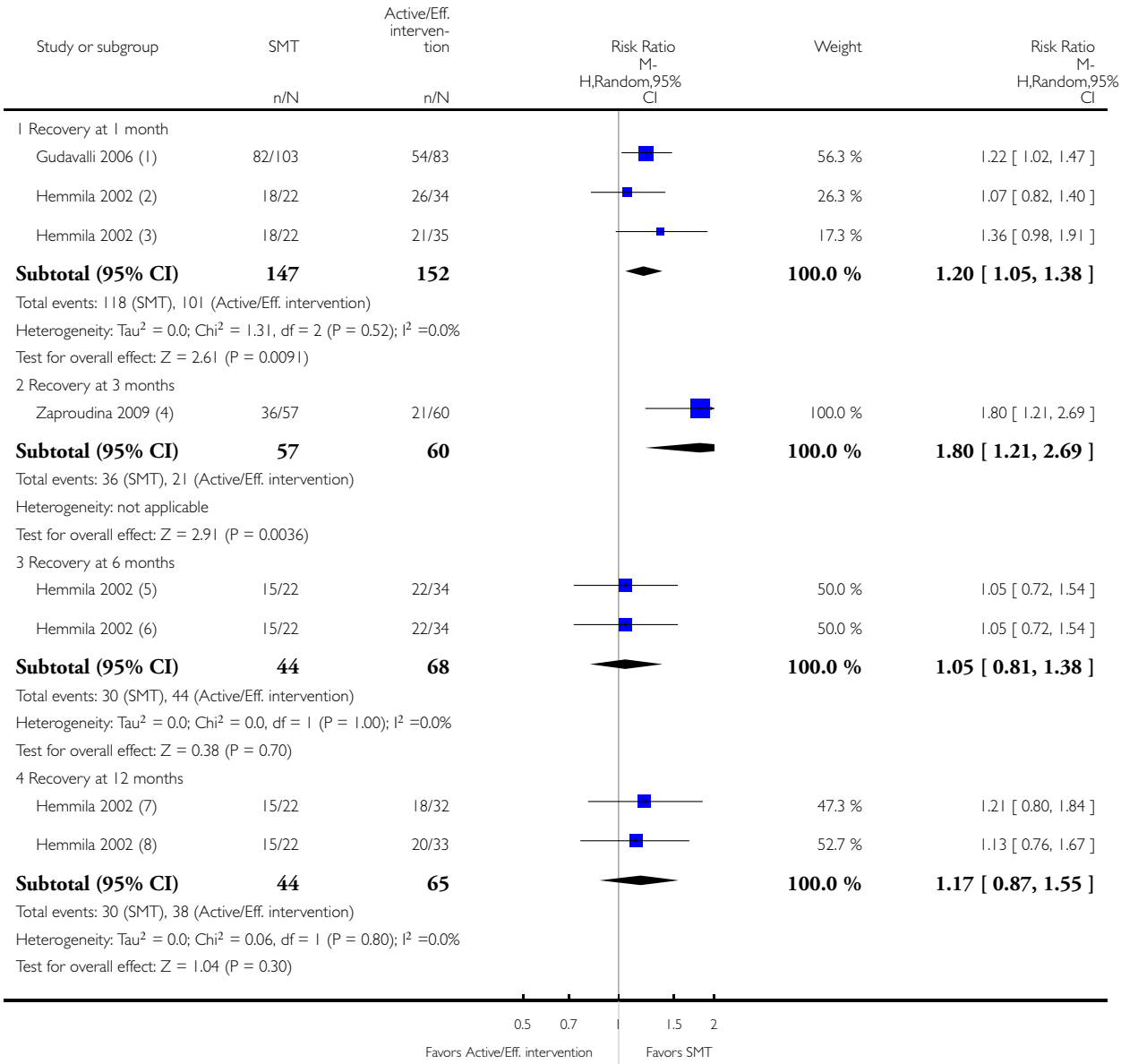
(32) + physical modalities

Analysis 5.3. Comparison 5 Subset of comparison 3. SMT vs. effective interventions, Outcome 3 Perceived recovery.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 5 Subset of comparison 3. SMT vs. effective interventions

Outcome: 3 Perceived recovery



(1) Question posed to patients, "Overall, how much were you helped?"; answers were dichotomized by "quite a bit" % "very much" to "a little bit", "not at all" % "not sure".

(8) vs.physiotherapy

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Study or subgroup	SMT n/N	Active/Eff. intervention n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
(2) SMT vs. physiotherapy; no. of patients improved					
(3) SMT vs. exercise					
(4) Bone-setting vs. physiotherapy; Global assessment on 11-point scale - dichotomized into <8 vs. >=8; post-tx. =˜3 mos. post-baseline					
(5) vs. physiotherapy					
(6) vs. exercise					
(7) vs. exercise					
(8) vs.physiotherapy					

Analysis 5.4. Comparison 5 Subset of comparison 3. SMT vs. effective interventions, Outcome 4 Return to work.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 5 Subset of comparison 3. SMT vs. effective interventions

Outcome: 4 Return to work

Study or subgroup	SMT n/N	Active/Eff. intervention n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Return to work at 3 months					
Brnfort 1996 (1)	61/71	43/52		100.0 %	1.04 [0.89, 1.21]
Subtotal (95% CI)	**71**	**52**		**100.0 %**	**1.04 [0.89, 1.21]**
Total events: 61 (SMT), 43 (Active/Eff. intervention)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.48 (P = 0.63)					
2 Return to work at 12 months					
Brnfort 1996	47/52	30/38		33.0 %	1.14 [0.95, 1.38]
Gudavalli 2006 (2)	90/107	65/84		57.0 %	1.09 [0.94, 1.25]
Hemmila 2002 (3)	12/22	16/32		4.3 %	1.09 [0.65, 1.83]
Hemmila 2002 (4)	12/22	22/32		5.7 %	0.79 [0.51, 1.24]
Subtotal (95% CI)	**203**	**186**		**100.0 %**	**1.09 [0.98, 1.21]**
Total events: 161 (SMT), 133 (Active/Eff. intervention)					
Heterogeneity: Tau^2 = 0.0; Chi^2 = 2.34, df = 3 (P = 0.50); I^2 =0.0%					
Test for overall effect: Z = 1.51 (P = 0.13)					
(4) SMT vs. physiotherapy; no. not sick-listed the year after therapy					

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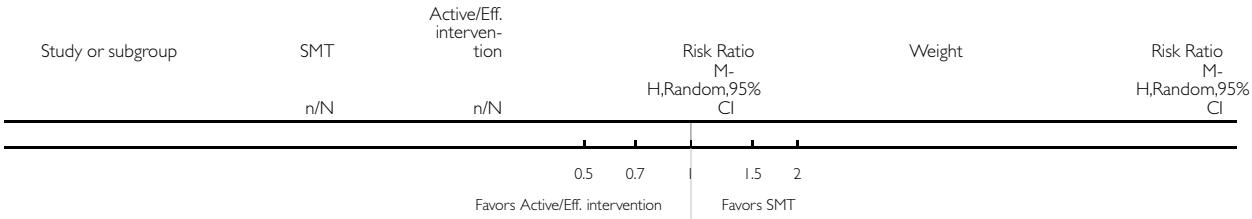


(1) SMT vs. NSAIDs; no. who returned to work at full or reduced capacity.

(2) SMT (flexion-distraction) vs. exercise; no. that did not take sick-leave due to LBP

(3) SMT vs. exercise; no. not sick-listed the year after therapy

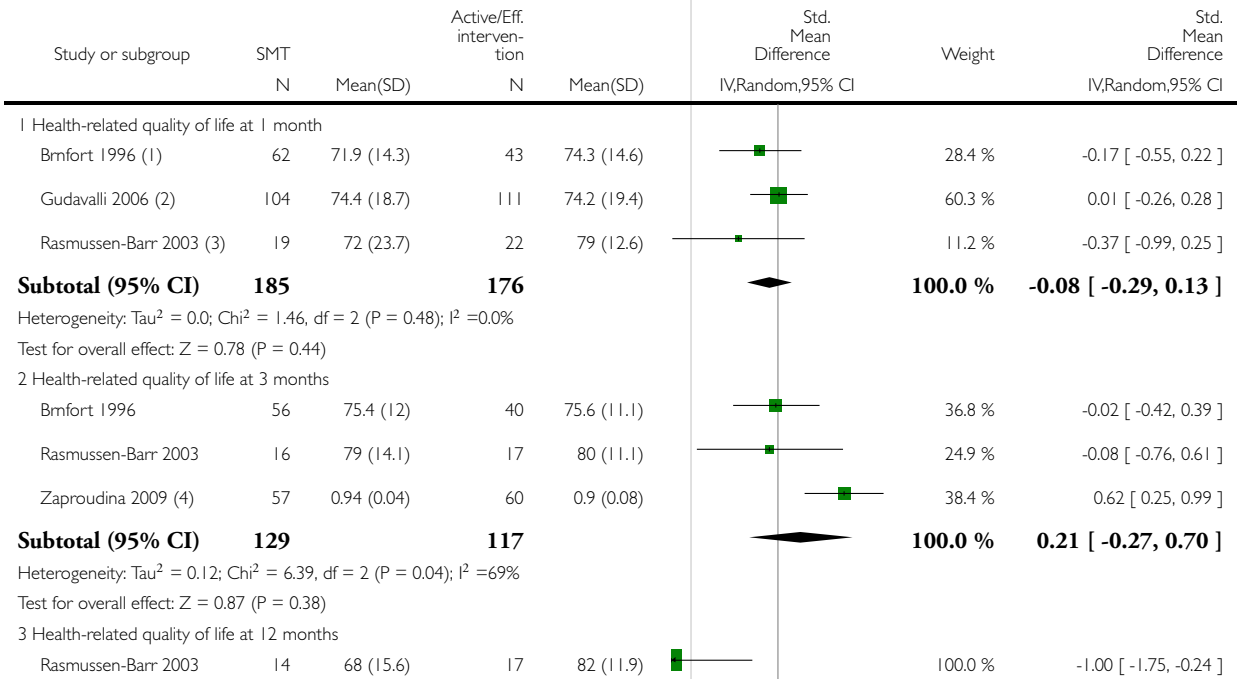
(4) SMT vs. physiotherapy; no. not sick-listed the year after therapy

Analysis 5.5. Comparison 5 Subset of comparison 3. SMT vs. effective interventions, Outcome 5 Health-related Quality of Life.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 5 Subset of comparison 3. SMT vs. effective interventions

Outcome: 5 Health-related Quality of Life



(4) Bone-setting vs. physio; HRQoL (15D) = Health-related Quality of Life: range=0-1, where 1=healthy population; 1 mos. post-tx. = ~3 mos. post-baseline

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Study or subgroup	SMT N	Mean(SD)	Active/Eff. interven-tion N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
Subtotal (95% CI)	**14**		**17**			**100.0 %**	**-1.00 [-1.75, -0.24]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.59 (P = 0.0097)							

(1) SMT + exercise vs. NSAIDs + exercise; Global General Health Status (as measured by COOP Chart scores); 0-100 where 100 = optimal health

(2) Mobilization vs. exercise therapy; SF-36 (general health subscale); change scores presented; SD from baseline used; per-protocol data - only available

(3) Manual ther. vs. stabilization training; General health - 10 cm VAS - Best to worst health - but converted here; median (IQR) converted to mean (SD)

(4) Bone-setting vs. physio; HRQoL (15D) = Health-related Quality of Life: range=0-1, where 1=healthy population; 1 mos. post-tx. = ~3 mos. post-baseline

Analysis 6.1. Comparison 6 SMT + intervention vs. intervention alone, Outcome 1 Pain.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 6 SMT + intervention vs. intervention alone

Outcome: 1 Pain

Study or subgroup	SMT+ another intervention N	Mean(SD)	Intervention alone N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Pain at 1 month							
Hsieh 2002 (1)	48	20.4 (13.5)	49	27.8 (18.2)		61.0 %	-7.40 [-13.77, -1.03]
Licciardone 2003 (2)	42	37.7 (26.2)	17	46.5 (20.7)		15.5 %	-8.80 [-21.43, 3.83]
Rasmussen 2008 (3)	35	30 (22.2)	37	30 (22.2)		23.5 %	0.0 [-10.26, 10.26]
Subtotal (95% CI)	**125**		**103**			**100.0 %**	**-5.88 [-10.85, -0.90]**
Heterogeneity: Tau^2 = 0.0; Chi^2 = 1.69, df = 2 (P = 0.43); I^2 =0.0%							
Test for overall effect: Z = 2.32 (P = 0.021)							
2 Pain at 3 months							
Licciardone 2003 (4)	36	31 (24.5)	16	45.2 (20.1)		10.8 %	-14.20 [-26.89, -1.51]
UK BEAM trial 2004 (5)	275	40.9 (24.87)	239	49.59 (25.04)		45.7 %	-8.69 [-13.02, -4.36]
UK BEAM trial 2004 (6)	246	40.76 (24.94)	204	44.73 (24.42)		43.5 %	-3.97 [-8.55, 0.61]
Subtotal (95% CI)	**557**		**459**			**100.0 %**	**-7.23 [-11.72, -2.74]**
Heterogeneity: Tau^2 = 6.61; Chi^2 = 3.50, df = 2 (P = 0.17); I^2 =43%							
Test for overall effect: Z = 3.16 (P = 0.0016)							
3 Pain at 6 months							
(8) Best care + SMT vs. Best care alone							

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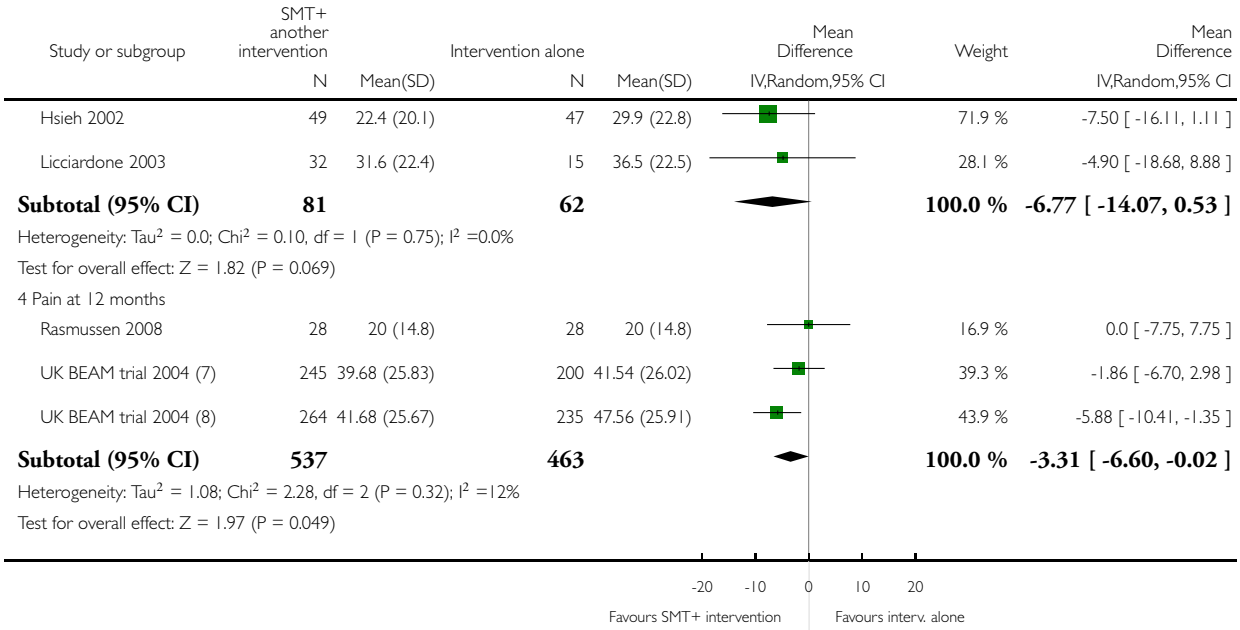


(1) chiropractic SMT + myofascial therapy vs. myofascial therapy alone

(2) Osteopathic SMT + usual care vs. usual care alone

(3) orthomanual/medical physician SMT + extension exercises vs. extension exercises alone; median (IQR) converted to mean (SD)

(4) see ref.2

(5) Best care + SMT vs. Best care alone; Modified von Korff - pain scale only

(6) Best care + exercise + SMT vs. Best care + exercise; Modified von Korff - pain scale only

(7) Best care + exercise + SMT vs. Best care + exercise

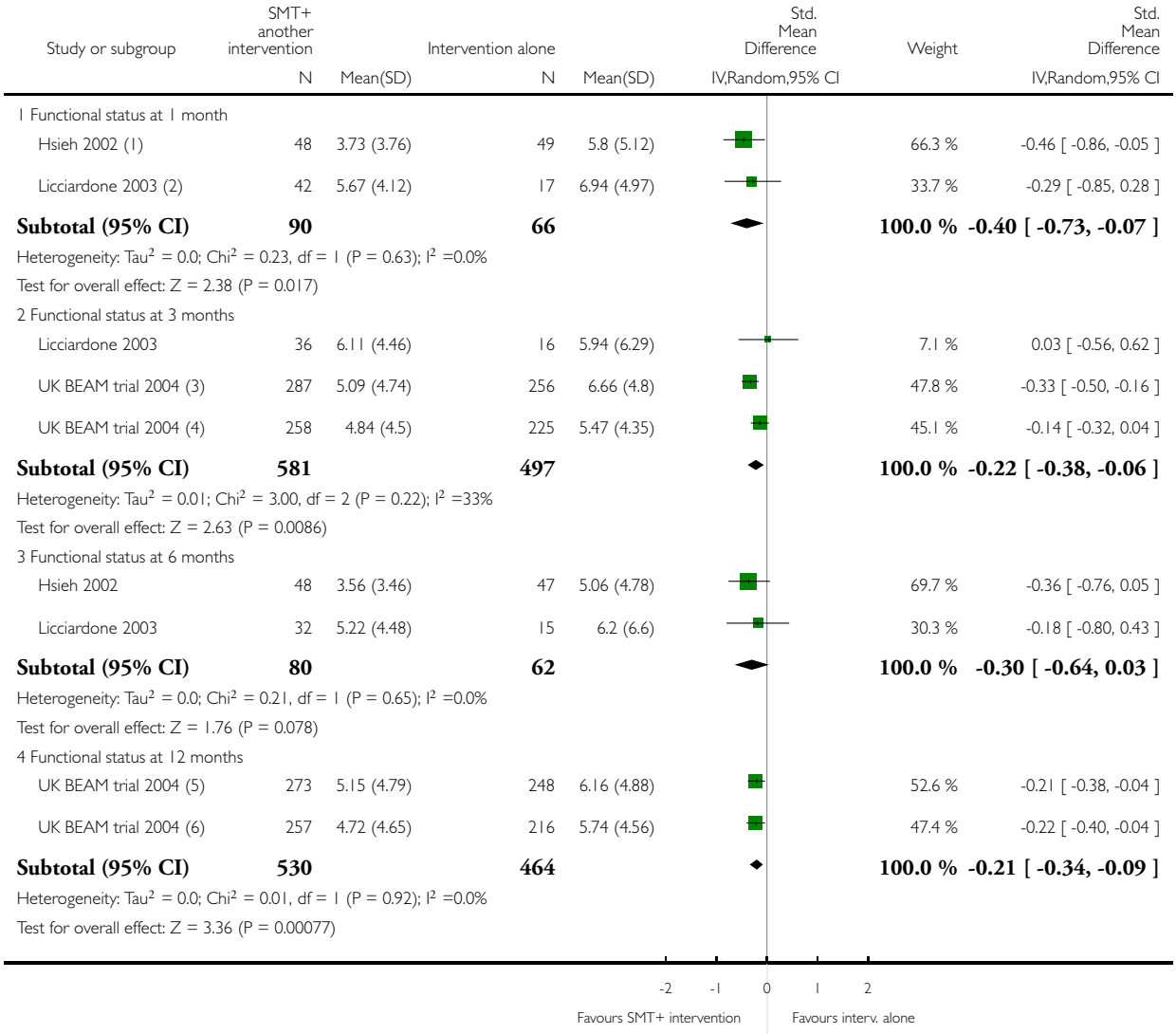
(8) Best care + SMT vs. Best care alone

Analysis 6.2. Comparison 6 SMT + intervention vs. intervention alone, Outcome 2 Functional status.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 6 SMT + intervention vs. intervention alone

Outcome: 2 Functional status



(1) SMT + myofascial therapy vs. myofascial therapy alone; RMDQ

(2) OMT + usual care vs. usual care alone;

(3) Best care + SMT vs. Best care alone; RMDQ

(4) Best care + exercise + SMT vs. Best care + exercise; RMDQ

(5) Best care + SMT vs. SMT alone

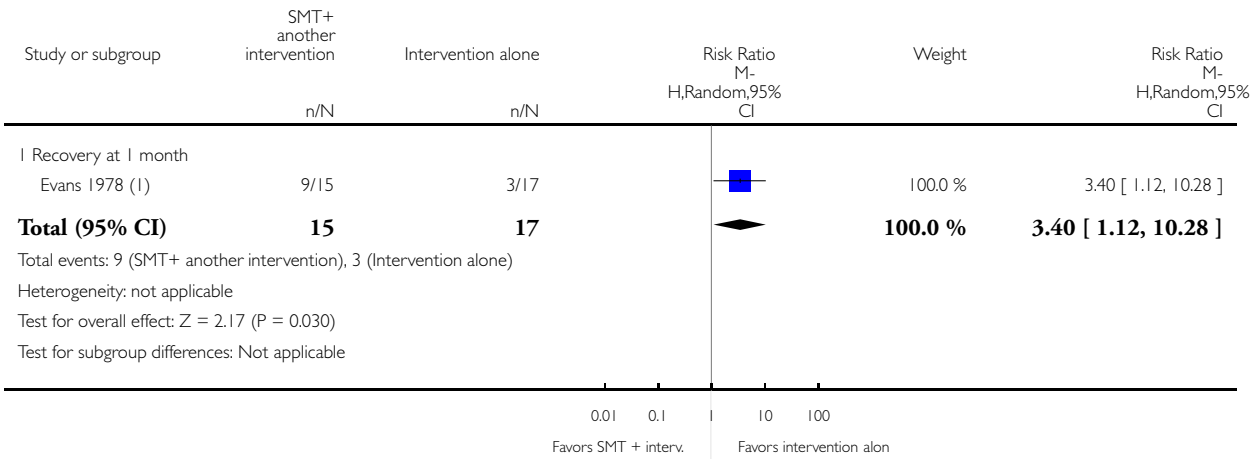
(6) Best care + exercise + SMT vs. Best care + exercise

Analysis 6.3. Comparison 6 SMT + intervention vs. intervention alone, Outcome 3 Perceived recovery.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 6 SMT + intervention vs. intervention alone

Outcome: 3 Perceived recovery



(1) SMT/OMT? medical manpiulator? + analgesics (codeine) vs. analgesics alone

Analysis 7.1. Comparison 7 Subset of comparison 3. SMT vs. any other intervention - studies w/ low RoB only, Outcome 1 Pain.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 7 Subset of comparison 3. SMT vs. any other intervention - studies w/ low RoB only

Outcome: 1 Pain

Study or subgroup	SMT N	SMT Mean(SD)	Other intervention N	Other intervention Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Pain at 1 month							
Brnfort 1996 (1)	62	34 (19)	43	36 (22)		7.4 %	-2.00 [-10.10, 6.10]
Hemmila 2002 (2)	22	30.5 (15)	34	27 (15)		7.5 %	3.50 [-4.54, 11.54]
Hemmila 2002 (3)	22	30.5 (15)	35	30 (15)		7.5 %	0.50 [-7.50, 8.50]
Hondras 2009 (4)	90	29.49 (19.29)	16	33.47 (19.49)		4.9 %	-3.98 [-14.33, 6.37]
Hondras 2009 (5)	83	27.63 (19.31)	16	33.47 (19.49)		4.8 %	-5.84 [-16.25, 4.57]
Hsieh 2002 (6)	22	25.8 (19.3)	49	27.8 (18.2)		5.6 %	-2.00 [-11.54, 7.54]
Hsieh 2002 (7)	22	25.8 (19.3)	42	21.3 (12.8)		6.3 %	4.50 [-4.45, 13.45]
Hurwitz 2002 (8)	169	34 (19)	169	36 (19)		18.9 %	-2.00 [-6.05, 2.05]
Hurwitz 2002 (9)	169	31 (18)	168	35 (20)		18.8 %	-4.00 [-8.06, 0.06]
Skillgate 2007 (10)	92	36 (14.4)	80	44 (13.4)		18.4 %	-8.00 [-12.16, -3.84]
Subtotal (95% CI)	**753**		**652**			**100.0 %**	**-2.76 [-5.19, -0.32]**
Heterogeneity: $Tau^2 = 3.91$; $Chi^2 = 12.35$, df = 9 (P = 0.19); $I^2 = 27\%$							
Test for overall effect: Z = 2.22 (P = 0.027)							
2 Pain at 3 months							
Brnfort 1996	56	27 (20)	40	35 (22)		12.8 %	-8.00 [-16.60, 0.60]
Ferreira 2007	77	41 (26)	147	44 (24.5)		15.7 %	-3.00 [-10.03, 4.03]
Hemmila 2002 (11)	22	30 (15)	34	27.5 (15)		13.8 %	2.50 [-5.54, 10.54]
Hemmila 2002 (12)	22	30 (15)	35	31 (15)		13.9 %	-1.00 [-9.00, 7.00]
Skillgate 2007	89	26 (14.4)	73	37 (13.4)		22.1 %	-11.00 [-15.29, -6.71]
UK BEAM trial 2004 (13)	275	40.9 (24.87)	204	44.73 (24.42)		21.7 %	-3.83 [-8.29, 0.63]
Subtotal (95% CI)	**541**		**533**			**100.0 %**	**-4.55 [-8.68, -0.43]**
Heterogeneity: $Tau^2 = 15.28$; $Chi^2 = 12.68$, df = 5 (P = 0.03); $I^2 = 61\%$							
Test for overall effect: Z = 2.16 (P = 0.031)							
3 Pain at 6 months							
Ferreira 2007	72	43 (26)	139	45.6 (26)		10.2 %	-2.60 [-10.00, 4.80]
Hemmila 2002 (14)	22	25 (15)	35	30 (15)		8.7 %	-5.00 [-13.00, 3.00]
Hemmila 2002 (15)	22	25 (15)	34	26 (15)		8.6 %	-1.00 [-9.04, 7.04]
(21) vs. medical care only							

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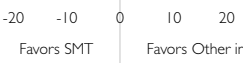
Study or subgroup	SMT N	SMT Mean(SD)	Other intervention N	Other intervention Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
Hsieh 2002 (16)	20	24 (24.1)	42	22.9 (19.8)		3.8 %	1.10 [-11.04, 13.24]
Hsieh 2002 (17)	20	24 (24.1)	47	29.9 (22.8)		3.6 %	-5.90 [-18.31, 6.51]
Hurwitz 2002 (18)	163	18 (18)	159	22 (20)		32.1 %	-4.00 [-8.16, 0.16]
Hurwitz 2002 (19)	165	26 (19)	165	28.5 (19)		33.1 %	-2.50 [-6.60, 1.60]
Subtotal (95% CI)	**484**		**621**			**100.0 %**	**-3.07 [-5.42, -0.71]**
Heterogeneity: Tau² = 0.0; Chi² = 1.41, df = 6 (P = 0.97); I² =0.0%							
Test for overall effect: Z = 2.55 (P = 0.011)							
4 Pain at 12 months							
Ferreira 2007	73	49 (27)	138	50.6 (28.5)		9.6 %	-1.60 [-9.41, 6.21]
Hurwitz 2002 (20)	156	27.5 (18)	148	28 (20)		32.0 %	-0.50 [-4.78, 3.78]
Hurwitz 2002 (21)	153	32.5 (19)	153	34 (19)		32.4 %	-1.50 [-5.76, 2.76]
UK BEAM trial 2004	264	41.68 (25.67)	200	41.54 (26.02)		26.0 %	0.14 [-4.61, 4.89]
Subtotal (95% CI)	**646**		**639**			**100.0 %**	**-0.76 [-3.19, 1.66]**
Heterogeneity: Tau² = 0.0; Chi² = 0.31, df = 3 (P = 0.96); I² =0.0%							
Test for overall effect: Z = 0.62 (P = 0.54)							



(1) HVLA-SMT + strength exercises vs. NSAID + strength exercises;

(2) vs. physiotherapy

(3) vs. exercise

(4) HVLA-SMT vs medical care; adjusted scores from linear effects model; data from author

(5) LVVA-SMT (flexion-distraction) vs. medical care; adjusted scores from linear effects model; data from author

(6) SMT vs. Myofascial therapy

(7) SMT vs. Back school

(8) chiropractic care only vs. medical care only; data from 6 weeks; average pain; data estimated from graphs; SD used from baseline

(9) chiropractic care +physical modalities (DCPm) vs. medical care + physical therapy (MDpt); data from 6 weeks; average pain; data estimated from graphs; SD used from baseline

(10) Naprapathy vs. std. medical care; data provided by author

(11) vs physiotherapy

(12) vs exercise

(13) Best care + SMT vs. Best care + exercise

(14) vs exercise

(15) vs physiotherapy

(16) vs. back school

(17) vs. myofascial therapy

(18) physical modalities (DCPm)

(19) vs. medical care only

(20) +physical modalities (DCPm)

(21) vs. medical care only

Analysis 7.2. Comparison 7 Subset of comparison 3. SMT vs. any other intervention - studies w/ low RoB only, Outcome 2 Functional status.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 7 Subset of comparison 3. SMT vs. any other intervention - studies w/ low RoB only

Outcome: 2 Functional status

Study or subgroup	SMT N	Mean(SD)	Other intervention N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
1 Functional status at 1 month							
Bmfort 1996 (1)	62	19.1 (19.3)	43	20.8 (17.8)		8.2 %	-0.09 [-0.48, 0.30]
Hemmila 2002 (2)	20	16.7 (11.6)	33	16.1 (7.7)		4.1 %	0.06 [-0.49, 0.62]
Hemmila 2002 (3)	20	16.7 (11.6)	29	16.2 (9.5)		3.9 %	0.05 [-0.52, 0.62]
Hondras 2009 (4)	87	4.35 (2.9)	16	6.42 (2.91)		4.3 %	-0.71 [-1.25, -0.17]
Hondras 2009 (5)	94	4.62 (2.91)	16	6.42 (2.91)		4.4 %	-0.61 [-1.15, -0.08]
Hsieh 2002 (6)	22	4.42 (4.92)	42	4.26 (3.52)		4.7 %	0.04 [-0.48, 0.55]
Hsieh 2002 (7)	22	4.42 (4.92)	49	5.8 (5.12)		4.9 %	-0.27 [-0.77, 0.24]
Hurwitz 2002 (8)	169	6.5 (5)	168	7.5 (5.4)		25.8 %	-0.19 [-0.41, 0.02]
Hurwitz 2002 (9)	169	6.8 (5.6)	169	7.3 (5.6)		26.0 %	-0.09 [-0.30, 0.12]
Skillgate 2007 (10)	92	1.9 (2.45)	80	2.4 (2.28)		13.6 %	-0.21 [-0.51, 0.09]
Subtotal (95% CI)	**757**		**645**			**100.0 %**	**-0.17 [-0.29, -0.06]**
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 9.25$, df = 9 (P = 0.41); $I^2 = 3\%$							
Test for overall effect: Z = 3.00 (P = 0.0027)							
2 Functional status at 3 months							
Bmfort 1996	56	15.1 (17.4)	40	20.9 (17)		11.7 %	-0.33 [-0.74, 0.07]
Ferreira 2007 (11)	77	7.9 (6)	147	8.8 (6)		16.8 %	-0.15 [-0.43, 0.13]
Hemmila 2002 (12)	22	18.6 (11.6)	33	14.1 (7.7)		8.1 %	0.47 [-0.08, 1.02]
Hemmila 2002 (13)	22	18.6 (11.6)	35	16.5 (9.5)		8.4 %	0.20 [-0.33, 0.73]
Hondras 2009 (14)	85	3.45 (4.03)	19	5.62 (4.05)		9.1 %	-0.53 [-1.04, -0.03]
Hondras 2009 (15)	93	4.11 (4.05)	19	5.62 (4.05)		9.2 %	-0.37 [-0.87, 0.13]
Skillgate 2007	90	1.3 (2.45)	73	2.4 (2.28)		15.2 %	-0.46 [-0.77, -0.15]
UK BEAM trial 2004 (16)	287	5.09 (4.74)	225	5.47 (4.35)		21.5 %	-0.08 [-0.26, 0.09]
Subtotal (95% CI)	**732**		**591**			**100.0 %**	**-0.18 [-0.37, 0.01]**
Heterogeneity: $Tau^2 = 0.03$; $Chi^2 = 14.64$, df = 7 (P = 0.04); $I^2 = 52\%$							
Test for overall effect: Z = 1.89 (P = 0.059)							
3 Functional status at 6 months							
Ferreira 2007	72	7.7 (6.2)	139	9.3 (6.7)		16.1 %	-0.24 [-0.53, 0.04]
(28) vs. medical care only							

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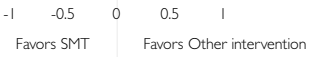
Study or subgroup	SMT N	SMT Mean(SD)	Other intervention N	Other intervention Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
Hemmila 2002 (17)	22	14.3 (11.6)	33	15.9 (9.5)		4.5 %	-0.15 [-0.69, 0.39]
Hemmila 2002 (18)	22	14.3 (11.6)	33	13.4 (7.7)		4.5 %	0.09 [-0.45, 0.63]
Hondras 2009 (19)	86	3.44 (4.39)	17	5.34 (4.27)		4.8 %	-0.43 [-0.96, 0.09]
Hondras 2009 (20)	89	4.06 (4.36)	17	5.34 (4.27)		4.8 %	-0.29 [-0.81, 0.23]
Hsieh 2002 (21)	21	3.29 (4.73)	42	3.48 (3.86)		4.8 %	-0.05 [-0.57, 0.48]
Hsieh 2002 (22)	21	3.29 (4.73)	47	5.06 (4.78)		4.9 %	-0.37 [-0.89, 0.15]
Hurwitz 2002 (23)	163	3.8 (5)	159	3.5 (5.4)		27.5 %	0.06 [-0.16, 0.28]
Hurwitz 2002 (24)	165	4.1 (5.6)	165	4.8 (5.6)		28.1 %	-0.12 [-0.34, 0.09]
Subtotal (95% CI)	**661**		**652**			**100.0 %**	**-0.12 [-0.23, 0.00]**
Heterogeneity: Tau² = 0.0; Chi² = 6.61, df = 8 (P = 0.58); I² =0.0%							
Test for overall effect: Z = 1.99 (P = 0.047)							
4 Functional status at 12 months							
Ferreira 2007	73	9.2 (6.6)	138	9.2 (6.7)		13.8 %	0.0 [-0.28, 0.28]
Hemmila 2002 (25)	22	15.3 (11.6)	32	17.2 (9.5)		3.7 %	-0.18 [-0.72, 0.36]
Hemmila 2002 (26)	22	15.3 (11.6)	32	13.7 (7.7)		3.7 %	0.17 [-0.38, 0.71]
Hurwitz 2002 (27)	156	6.2 (5)	148	6 (5.4)		21.9 %	0.04 [-0.19, 0.26]
Hurwitz 2002 (28)	153	6.6 (5.6)	153	7.1 (5.6)		22.1 %	-0.09 [-0.31, 0.14]
UK BEAM trial 2004	273	5.15 (4.79)	216	5.74 (4.56)		34.7 %	-0.13 [-0.30, 0.05]
Subtotal (95% CI)	**699**		**719**			**100.0 %**	**-0.06 [-0.16, 0.05]**
Heterogeneity: Tau² = 0.0; Chi² = 2.34, df = 5 (P = 0.80); I² =0.0%							
Test for overall effect: Z = 1.03 (P = 0.30)							



(1) HVLA-SMT + strength exercises vs. NSAID + strength exercises; RMDQ

(2) SMT vs. physiotherapy; change scores presented in text; SD's used from baseline; number of SMT subjects was halved; Oswestry.

(3) SMT vs. exercise; change scores presented; SD's used from baseline; number of SMT subjects was halved; Oswestry.

(4) LVVA-SMT (flexion-distraction) vs. medical care; RMDQ; adjusted scores from linear effects model - data from author

(5) HVLA-SMT vs medical care; RMDQ; adjusted scores from linear effects model - data from author

(6) HVLA-SMT vs. back school; RMDQ

(7) HVLA-SMT vs. Myofascial therapy; RMDQ

(8) chiropractic care + physical modalities vs. medical care + physical therapy; data from 6 weeks; RMDQ; data estimated from graphs; SD used from baseline score

(9) chiropractic care only vs. medical care only; data from 6 weeks; RMDQ; data estimated from graphs; SD used from baseline score

(10) Naprapathy vs. std. medical care; data provided by author; CPQ - von Korff scale

(11) SMT vs. general + motor control exercise; RMDQ

(12) vs. physiotherapy

(13) vs. exercise

(14) LVVA-SMT (flexion-distraction) vs. medical care;

(15) HVLA-SMT vs medical care

(16) Best care + SMT vs. Best care + exercise

(28) vs. medical care only

(*Continued* . . .)

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Study or subgroup	SMT N	SMT Mean(SD)	Other intervention N	Other intervention Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
(17) vs. exercise							
(18) vs. physiotherapy							
(19) LVVA-SMT (flexion-distraction) vs. medical care							
(20) HVLA-SMT vs medical care							
(21) vs. back school							
(22) vs. myofascial therapy							
(23) + physical modalities							
(24) vs. medical care only							
(25) vs. exercise							
(26) vs. physiotherapy							
(27) + physical modalities							
(28) vs. medical care only							

Analysis 7.3. Comparison 7 Subset of comparison 3. SMT vs. any other intervention - studies w/ low RoB only, Outcome 3 Perceived recovery.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 7 Subset of comparison 3. SMT vs. any other intervention - studies w/ low RoB only

Outcome: 3 Perceived recovery

Study or subgroup	SMT n/N	Other intervention n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Recovery at 1 month					
Hemmila 2002 (1)	18/22	21/35		41.7 %	1.36 [0.98, 1.91]
Hemmila 2002 (2)	18/22	26/34		58.3 %	1.07 [0.82, 1.40]
Subtotal (95% CI)	**44**	**69**		**100.0 %**	**1.18 [0.93, 1.50]**
Total events: 36 (SMT), 47 (Other intervention)					
Heterogeneity: $Tau^2 = 0.01$; $Chi^2 = 1.25$, df = 1 (P = 0.26); $I^2 = 20\%$					
Test for overall effect: Z = 1.39 (P = 0.16)					
2 Recovery at 6 months					
Hemmila 2002 (3)	15/22	22/34		50.0 %	1.05 [0.72, 1.54]
Hemmila 2002 (4)	15/22	22/34		50.0 %	1.05 [0.72, 1.54]
Subtotal (95% CI)	**44**	**68**		**100.0 %**	**1.05 [0.81, 1.38]**
Total events: 30 (SMT), 44 (Other intervention)					
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.0$, df = 1 (P = 1.00); $I^2 = 0.0\%$					
(6) vs. exercise					

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Study or subgroup	SMT n/N	Other intervention n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Test for overall effect: Z = 0.38 (P = 0.70)					
3 Recovery at 12 months					
Hemmila 2002 (5)	15/22	20/33		52.7 %	1.13 [0.76, 1.67]
Hemmila 2002 (6)	15/22	18/32		47.3 %	1.21 [0.80, 1.84]
Subtotal (95% CI)	**44**	**65**		**100.0 %**	**1.17 [0.87, 1.55]**
Total events: 30 (SMT), 38 (Other intervention)					
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.06$, df = 1 (P = 0.80); $I^2 = 0.0\%$					
Test for overall effect: Z = 1.04 (P = 0.30)					

(1) SMT vs. exercise

(2) SMT vs. physiotherapy; no. of patients improved

(3) vs. exercise

(4) vs. physiotherapy

(5) vs.physiotherapy

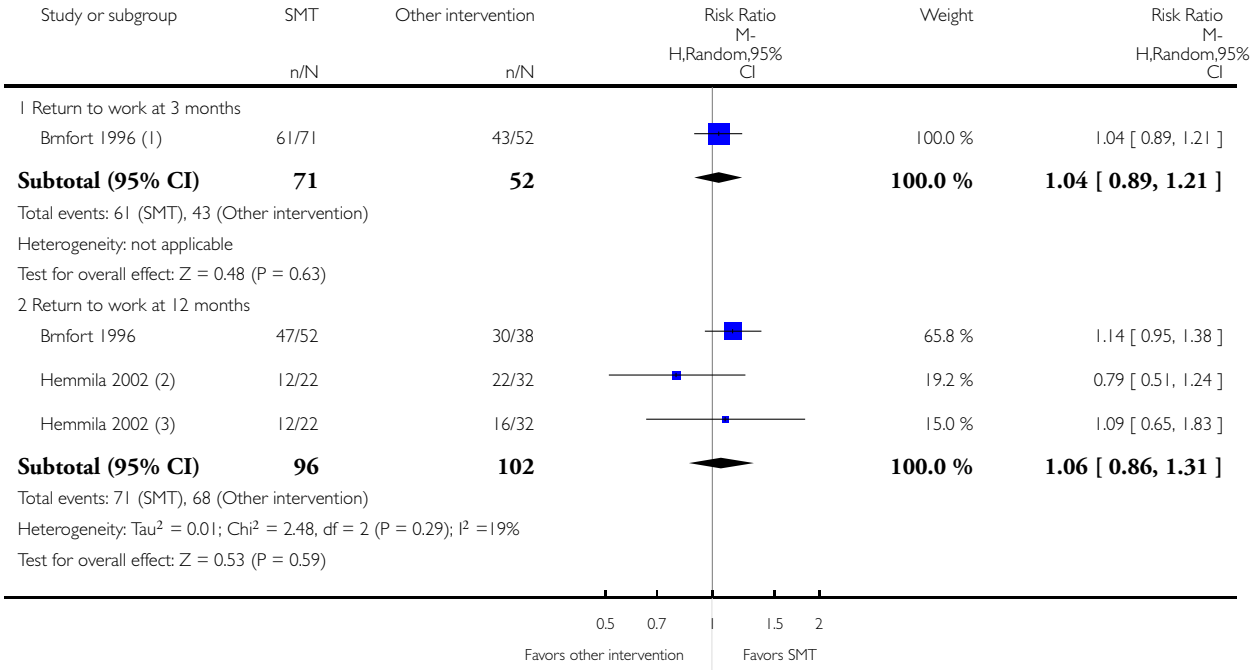
(6) vs. exercise

Analysis 7.4. Comparison 7 Subset of comparison 3. SMT vs. any other intervention - studies w/ low RoB only, Outcome 4 Return to work.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 7 Subset of comparison 3. SMT vs. any other intervention - studies w/ low RoB only

Outcome: 4 Return to work



(1) SMT vs. NSAIDs; no. who returned to work at full or reduced capacity.

(2) SMT vs. physiotherapy; no. not sick-listed the year after therapy

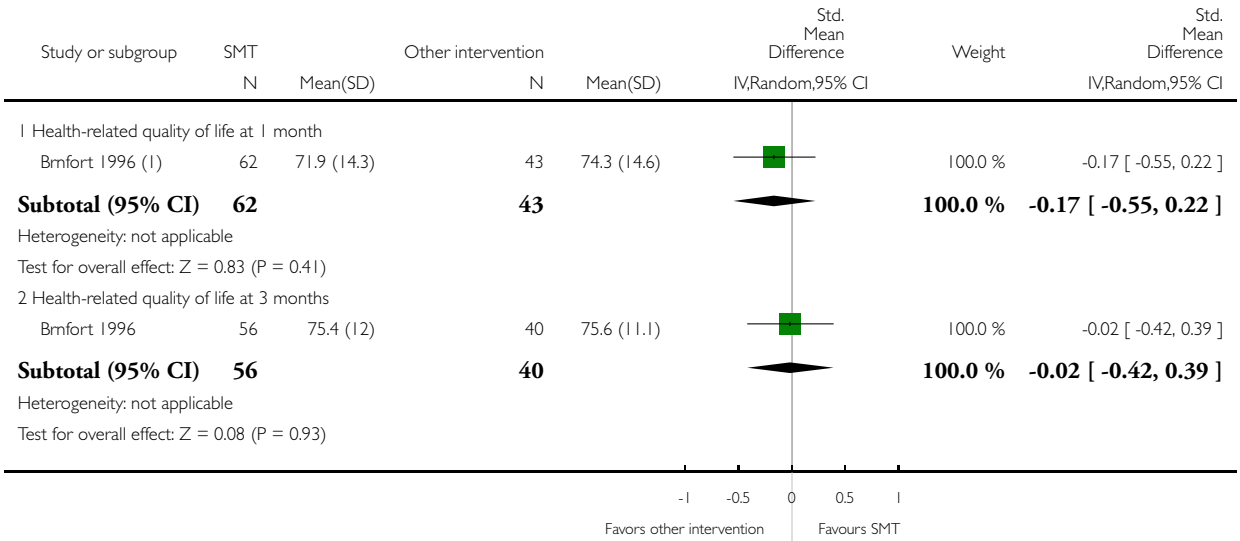
(3) SMT vs. exercise; no. not sick-listed the year after therapy

Analysis 7.5. Comparison 7 Subset of comparison 3. SMT vs. any other intervention - studies w/ low RoB only, Outcome 5 Health-related Quality of Life.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 7 Subset of comparison 3. SMT vs. any other intervention - studies w/ low RoB only

Outcome: 5 Health-related Quality of Life



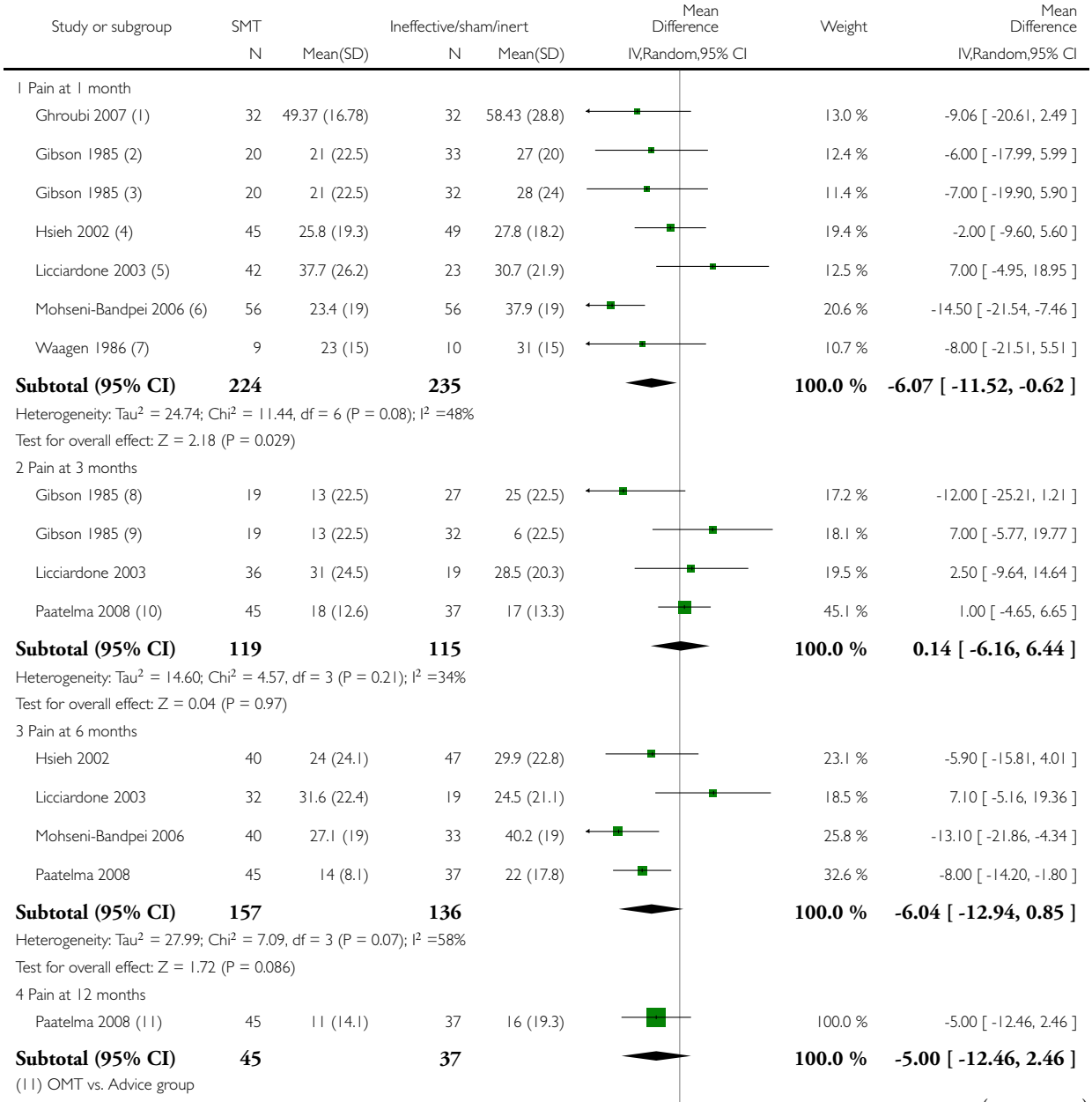
(1) SMT + exercise vs. NSAIDs + exercise; Global General Health Status (as measured by COOP Chart scores); 0-100 where 100 = optimal health

Analysis 8.1. Comparison 8 Subset of comparisons 1, 2 & 3. SMT vs. ineffective/sham/inert interventions, Outcome 1 Pain.

Review: Spinal manipulative therapy for chronic low-back pain

Comparison: 8 Subset of comparisons 1, 2 % 3. SMT vs. ineffective/sham/inert interventions

Outcome: 1 Pain



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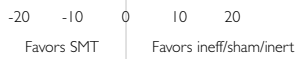
Study or subgroup	SMT N	SMT Mean(SD)	Ineffective/sham/inert N	Ineffective/sham/inert Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
Heterogeneity: not applicable							
Test for overall effect: Z = 1.31 (P = 0.19)							



(1) vs sham SMT

(2) vs detuned diathermy

(3) vs. diathermy; median (range) presented in text - and converted; daytime pain

(4) vs. Myofascial therapy

(5) vs sham SMT

(6) SMT + exercise vs. Ultrasound + exercise

(7) vs sham SMT

(8) vs. diathermy

(9) vs detuned diathermy

(10) OMT vs. Advice-group (counseling session + educational back booklet)

(11) OMT vs. Advice group

Analysis 8.2. Comparison 8 Subset of comparisons 1, 2 & 3. SMT vs. ineffective/sham/inert interventions, Outcome 2 Functional status.

Review: Spinal manipulative therapy for chronic low-back pain

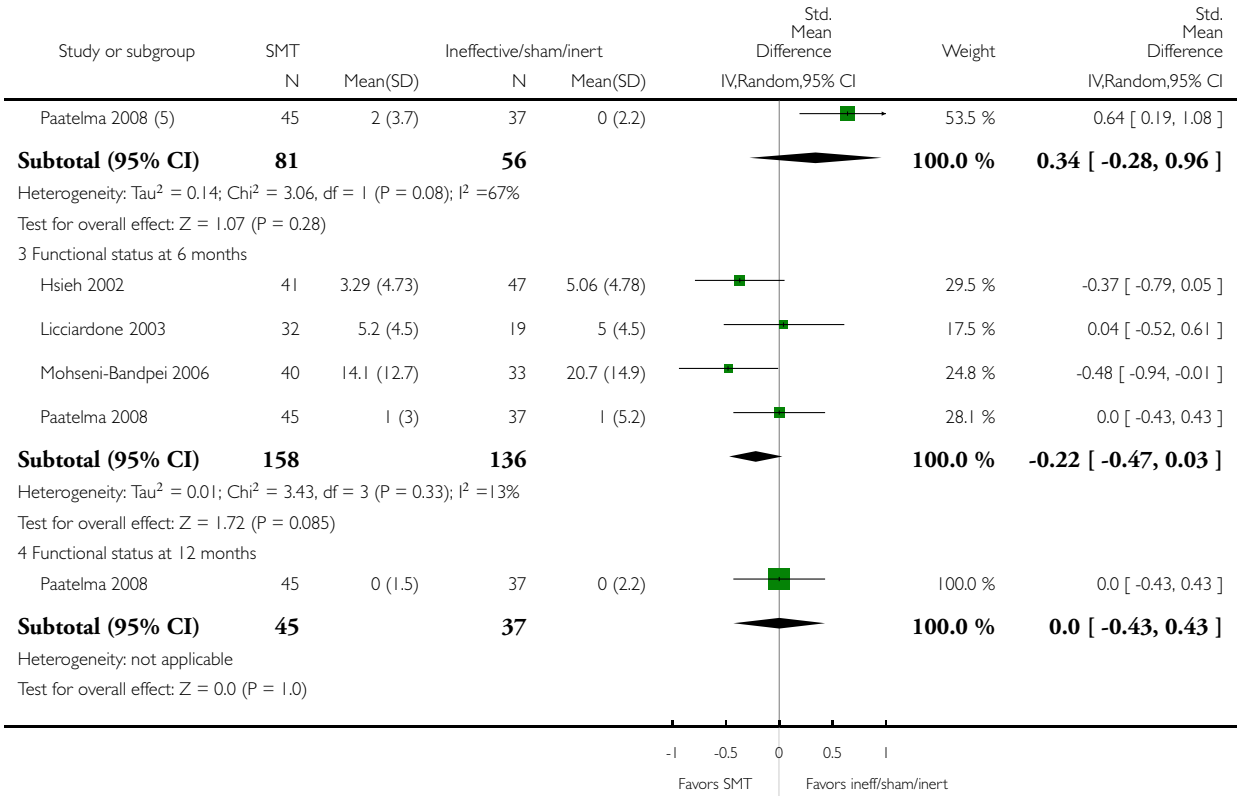
Comparison: 8 Subset of comparisons 1, 2 % 3. SMT vs. ineffective/sham/inert interventions

Outcome: 2 Functional status

Study or subgroup	SMT N	SMT Mean(SD)	Ineffective/sham/inert N	Ineffective/sham/inert Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
1 Functional status at 1 month							
Hsieh 2002 (1)	45	4.42 (4.92)	49	5.8 (5.12)		36.2 %	-0.27 [-0.68, 0.13]
Licciardone 2003 (2)	42	5.7 (4.1)	23	7.7 (4.8)		22.6 %	-0.45 [-0.97, 0.06]
Mohseni-Bandpei 2006 (3)	56	12.9 (12.7)	56	22.1 (14.9)		41.3 %	-0.66 [-1.04, -0.28]
Subtotal (95% CI)	**143**		**128**			**100.0 %**	**-0.47 [-0.72, -0.23]**
Heterogeneity: Tau² = 0.0; Chi² = 1.87, df = 2 (P = 0.39); I² =0.0%							
Test for overall effect: Z = 3.79 (P = 0.00015)							
2 Functional status at 3 months							
Licciardone 2003 (4)	36	6.1 (4.5)	19	6.1 (4.1)		46.5 %	0.0 [-0.56, 0.56]
(5) vs. advice group							

(*Continued* . . .)

(. . . *Continued*)



(1) vs. Myofascial therapy

(2) vs sham SMT

(3) SMT (Maitland) + exercise vs. ultrasound + exercise

(4) vs sham SMT

(5) vs. advice group

ADDITIONAL TABLES

Table 1. Specific clinical and treatment characteristics of the included studies

Author	Type radiating pain	Duration LBP: According to inclusion criteria	Duration LBP: Current episode for the population	Type manipulator (N=number of manipulators)	Type manipulation	Max. no. tx's SMT allowed and duration
Brønfort 1996	With or without radiation to one or both legs to the knee	> 6 wks	median: 2.5 yrs	Chiropractor (N = 5)	Manipulation	10 over 5 wks

Table 1. Specific clinical and treatment characteristics of the included studies (*Continued*)

Chown 2008	Without radiation	> 3 mo	unclear	Osteopathy & Manipulative therapy (N = ?)	Manipulation or MOB (depending upon grp. assignment)	5 over 3 mo
Evans 1978	With or without femoral or sciatic radiation	> 3 wks	median: 10 mo	Medical manipulator (N = 1)	Manipulation	3 over 3 wks
Ferreira 2007	With or without	> 3 mo	75% > 1 year	Physical therapists (N = ?)	MOB or manipulation; Maitland	12 over 8 wks
Ghroubi 2007	Without	> 6 mo	range: 16 to 19 mo	Manual or physical therapist? (N = 1)	Unclear; presumably manipulation?	4 over 4 wks
Gibson 1985	unclear	> 2 mo to < 12 mo	range: 4 to 4 ½ mo	Osteopath (N = 1)	Manipulation and MOB	4 over 4 wks
Goldby 2006	unclear	> 3 mo	mean: 11.7 yrs	Manual therapist (N = ?)	Unclear	10 over 10 wks?
Gudavalli 2006	With or without radiculopathy	> 3 mo	unclear	Chiropractor (N = ?)	MOB (flexion-distraction)	16 over 4 wks
Hemmila 2002	With or without radiation below knee	> 7 wks	range: 6.8 to 7.5 yrs	Bone-setter (N = 4)	Primarily MOB? No Manipulation	10 over 6 wks
Hondras 2009	Primarily (85%) with or without radiation to the knee	> 4 wks	range: 9.6 to 15.1 yrs	Chiropractor (N = 4)	Manipulation or MOB (flexion-distraction) (depending upon grp. assignment)	12 over 6 wks
Hsieh 2002	With or without leg pain, but no neurological signs	> 3 wks to < 6 mo	range: 10.7 to 11.8 wks	Chiropractor (N = ?)	Manipulation	9 over 3 wks
Hurwitz 2002	With or without leg pain	No restriction	58% >3mo	Chiropractor (N = 4)	Manipulation	? - at discretion of therapist
Koes 1992	With or without radiation to the knee	> 6 wks	median: 1 yr	Manual therapist (N = 7)	Manipulation and MOB	avg. 5 over 9 wks

Table 1. Specific clinical and treatment characteristics of the included studies (*Continued*)

Licciardone 2003	With or without sciatica, but no neurological signs	> 3 mo	range: 39% to 63% > 1 yr	Osteopath (N = ?)	Manipulation or MOB	7 over 5 mo
Mohseni-Bandpei 2006	Unclear	> 3 mo	range: 31 to 56 mo	Manual therapist (N = 1)	Manipulation (Maitland)	7 over 4 wks?
Muller 2005	Without	> 3 mo	range: 4 mo to 45 yrs	Chiropractor (N = 1?)	Manipulation	? - but equal per therapy grp.
Paatelma 2008	With or without sciatica	No restriction	> 50% symptoms > 3 mo	Orthopedic manual therapist (N = 1)	Manipulation or MOB	7 over ? wks mean: 6 tx's/grp
Pope 1994	Without sciatica	3 wks to 6 mo, preceded by 3 wk pain free episode	29% < 6 mo; 35% between 6 mo to 2 yrs; 36% > 2 years	Chiropractor (N = 5)	Manipulation	3 or more sessions/wk for 3 wks
Postacchini 1988	2 grps. = with and without radiation to knee	Grp.C = > 9 wks	Grp.C range: 9 to11 mo	Chiropractor (N = ?)	Manipulation?	12 over 6 wks
Rasmussen 2008	With or without radiation to the knee	> 3 mo	range: 8 to 17 mo	Medical manipulator (N = 1?)	Manipulation	3 over 4 wks
Rasmussen-Barr 2003	With or without radiation to the knee	> 6 wks	90% > 3 mo	Manual therapist (N = ?)	MOB	6 over 6 wks
Skillgate 2007	Unclear	> 2 wks	range: 72% to 78% > 3 mo	Naprapath (N = 8)	Manipulation or MOB	6 over 6 wks
UK BEAM trial 2004	(Primarily) with or without radiation to the knee	(Essentially) > 3 wks	59% > 3mo	Chiropractor, osteopath or physiotherapist (N = 84)	Manipulation or MOB	8 over 12 wks
Waagen 1986	With or without to the knee	> 3 wks	range: 2.5 to 2.8 yrs	Chiropractor (N = ?)	Manipulation	6 over 2 wks
Wilkey 2008	With or without radiation to the legs	>3 mo	range: 0.5 to 20 yrs	Chiropractor (N = ?)	Manipulation	16 over 8 wks

Table 1. Specific clinical and treatment characteristics of the included studies (*Continued*)

Zaproudina 2009	With or without radiation to the legs	> 3 mo	unclear	Bone-setters (N = ?)	MOB	5 over 10 wks

grp(s) = group(s); MOB = mobilization; wks = week(s); mo = month(s); yr = year(s); ? = unclear

APPENDICES

Appendix 1. CENTRAL Search Strategy

1. #1 MeSH descriptor Back explode all trees
2. #2 MeSH descriptor Buttocks, this term only
3. #3 MeSH descriptor Leg, this term only
4. #4 MeSH descriptor Back Pain explode tree 1
5. #5 MeSH descriptor Back Injuries explode all trees
6. #6 MeSH descriptor Low Back Pain, this term only
7. #7 MeSH descriptor Sciatica, this term only
8. #8 (low next back next pain)
9. #9 (lbp)
10. #10 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9)
11. #11 MeSH descriptor Musculoskeletal Manipulations explode all trees
12. #12 MeSH descriptor Chiropractic explode all trees
13. #13 manip*
14. #14 MeSH descriptor Osteopathic Medicine explode all trees
15. #15 osteopath*
16. #16 chiropract*
17. #17 (#11 OR #12 OR #13 OR #14 OR #15 OR #16)
18. #18 (#17 AND #10)
19. #19 (#18)

Appendix 2. MEDLINE Search Strategy

Yields 71 results for 2007-2008

1. Clinical Trial.pt.
2. randomized.ab,ti.
3. placebo.ab,ti.
4. dt.fs.
5. randomly.ab,ti.
6. trial.ab,ti.
7. groups.ab,ti.
8. or/1-7
9. Animals/
10. Humans/
11. 9 not (9 and 10)

12. 8 not 11
13. dorsalgia.ti,ab.
14. exp Back Pain/
15. backache.ti,ab.
16. (lumbar adj pain).ti,ab.
17. coccyx.ti,ab.
18. coccydynia.ti,ab.
19. sciatica.ti,ab.
20. sciatica/
21. spondylosis.ti,ab.
22. lumbago.ti,ab.
23. exp low back pain/
24. or/13-23
25. exp Manipulation, Chiropractic/
26. exp Manipulation, Orthopedic/
27. exp Manipulation, Osteopathic/
28. exp Manipulation, Spinal/
29. exp Musculoskeletal Manipulations/
30. exp Chiropractic/
31. manipulation.mp.
32. manipulate.mp.
33. exp Orthopedics/
34. exp Osteopathic Medicine/
35. or/25-34
36. 12 and 24 and 35
37. limit 36 to yr="2007 - 2008"

Appendix 3. EMBASE Search Strategy

Yields 123 for 2007-8

1. Clinical Article/
2. exp Clinical Study/
3. Clinical Trial/
4. Controlled Study/
5. Randomized Controlled Trial/
6. Major Clinical Study/
7. Double Blind Procedure/
8. Multicenter Study/
9. Single Blind Procedure/
10. Phase 3 Clinical Trial/
11. Phase 4 Clinical Trial/
12. crossover procedure/
13. placebo/
14. or/1-13
15. allocat$.mp.
16. assign$.mp.
17. blind$.mp.
18. (clinic$ adj25 (study or trial)).mp.
19. compar$.mp.
20. control$.mp.
21. cross?over.mp.
22. factorial$.mp.

23. follow?up.mp.
24. placebo$.mp.
25. prospectiv$.mp.
26. random$.mp.
27. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).mp.
28. trial.mp.
29. (versus or vs).mp.
30. or/15-29
31. 14 and 30
32. human/
33. Nonhuman/
34. exp ANIMAL/
35. Animal Experiment/
36. 33 or 34 or 35
37. 32 not 36
38. 31 not 36
39. 37 and 38
40. 38 or 39
41. dorsalgia.mp.
42. back pain.mp.
43. exp BACKACHE/
44. (lumbar adj pain).mp.
45. coccyx.mp.
46. coccydynia.mp.
47. sciatica.mp.
48. exp ISCHIALGIA/
49. spondylosis.mp.
50. lumbago.mp.
51. exp Low back pain/
52. or/41-51
53. exp CHIROPRACTIC/
54. exp Orthopedic Manipulation/
55. exp Manipulative Medicine/
56. exp Osteopathic Medicine/
57. manipulation.mp.
58. manipulate.mp.
59. exp Orthopedics/
60. osteopathy.mp.
61. or/53-60
62. 40 and 52 and 61
63. limit 62 to yr="2007 - 2008"

Appendix 4. CINAHL Search Strategy

Yields 44 for 2007-2008

1. Randomized Controlled Trials.mp.
2. clinical trial.pt.
3. exp Clinical Trials/
4. (clin$ adj25 trial$).tw.
5. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).tw.
6. exp PLACEBOS/
7. placebo$.tw.
8. random$.tw.
9. exp Study Design/
10. (latin adj square).tw.
11. exp Comparative Studies/
12. exp Evaluation Research/
13. Follow-Up Studies.mp.
14. exp Prospective Studies/
15. (control$ or prospectiv$ or volunteer$).tw.
16. Animals/
17. or/1-15
18. 17 not 16
19. dorsalgia.ti,ab.
20. exp Back Pain/
21. backache.ti,ab.
22. (lumbar adj pain).ti,ab.
23. coccyx.ti,ab.
24. coccydynia.ti,ab.
25. sciatica.ti,ab.
26. exp SCIATICA/
27. spondylosis.ti,ab.
28. lumbago.ti,ab.
29. exp low back pain/
30. or/19-29
31. exp CHIROPRACTIC/
32. exp MANIPULATION, CHIROPRACTIC/
33. exp MANIPULATION, ORTHOPEDIC/
34. exp MANIPULATION, OSTEOPATHIC/
35. manipulation.mp.
36. manipulate.mp.
37. exp Manual Therapy/
38. exp ORTHOPEDICS/
39. exp OSTEOPATHY/
40. or/31-39
41. 18 and 30 and 40
42. limit 41 to yr=”2007 - 2008“
43. from 42 keep 1-44

Appendix 5. Criteria for risk of bias assessment for RCTs

1. Was the method of randomisation adequate? This item was scored "yes" if a random (unpredictable) assignment sequence was used. Examples of adequate methods are coin toss (for studies with two groups), rolling a dice (for studies with two or more groups), drawing of balls of different colours, drawing of ballots with the study group labels from a dark bag, computer-generated random sequence, pre-ordered sealed envelops, sequentially-ordered vials, telephone call to a central office, and pre-ordered list of treatment assignments. Examples of inadequate methods are alternation, birth date, social security or insurance number, date in which subjects are invited to participate in the study and hospital registration number.

2. Was the treatment allocation concealed? This item was scored "yes" if the assignment was generated by an independent person not responsible for determining the eligibility of the patients. This means that the person had no information about the persons included in the trial and had no influence on the assignment sequence or on the decision about eligibility of the patient.

Was knowledge of the allocated interventions adequately prevented during the study?

3. Was the patient blinded to the intervention?

This item was scored "yes" if the index and control group(s) were indistinguishable for the patients or if the success of blinding was tested among the patients and it was successful.

4. Was the care provider blinded to the intervention? This item was scored "yes" if the index and control groups were indistinguishable for the care providers or if the success of blinding was tested among the care providers and it was successful. Comment: This item was always "no" for spinal manipulative therapy given that it is impossible to blind the clinician (unlike for example, medication).

5. Was the outcome assessor blinded to the intervention for the primary outcomes? This item was scored "yes" if the success of blinding was tested among the outcome assessors and it was successful. For patient-reported outcomes, in which the patient is the outcome assessor (e.g., pain, disability, recovery), blinding was considered adequate if participants were also blinded to treatment allocation. This is independent of whether the outcomes were recorded by an independent assessor blinded to allocation during a clinic visit or outcomes that were assessed via a questionnaire mailed to the patient. Studies limited to physiological outcomes were scored as a "no" as these were not considered relevant outcomes.

Were incomplete outcome data adequately addressed?

6. Was the drop-out rate described and acceptable? This item was scored "yes" if the number of participants who were included in the study but did not complete the observation period or were not included in the analysis were described and reasons given, or in absence of this information, the percentage of withdrawals and drop-outs did not exceed 20% for the short-term follow-up (3 months or less) and 30% for long-term follow-up (9 months or more) and was therefore, not likely to lead to substantial bias. Note: The percentage of participants retained in the study at the various follow-up measurements are reported in the risk of bias table.

7. Were all randomised participants analysed in the group to which they were allocated? This item was scored "yes" if all randomised patients were analysed in the group to which they were allocated for the primary outcomes and follow-up measurements, regardless of non-compliance and co-interventions. This excludes missing values, meaning imputation (by whatever means) was not required.

8. Are reports of the study free of suggestion of selective outcome reporting? This item was scored "yes" if all the results from all pre-specified outcomes were adequately reported. This determination was made by comparing the protocol (if available) with the full-report/publication or in the absence of the protocol, articles were assessed as "yes" if all three primary outcomes (i.e. pain, back-pain specific functional status/disability, and recovery) were reported.

Other sources of potential bias:

9. Were the groups similar at baseline regarding the most important prognostic indicators? This item was scored "yes" if the groups were similar at baseline regarding the main demographic factors (e.g. age, gender), duration and severity of complaints and value of the main outcome measure(s).

10. Were co-interventions avoided or similar? This item was scored "yes" if there were no co-interventions or they were similar between the index and control group(s).

11. Was the compliance acceptable in all groups? This item was scored "yes" if the compliance with the intervention was considered acceptable based upon the reported intensity, duration, number and frequency of sessions for both the index and control group(s). For example, spinal manipulative therapy is usually administered over several sessions; therefore, it was necessary to assess how many sessions had been prescribed for the patients *a priori* and whether they attended (most) of these sessions.

12. Was the timing of the outcome assessment similar in all groups? This item was scored "yes" if the timing of the outcome assessment(s) were identical for all groups and for all important outcome measures.

WHAT'S NEW

Last assessed as up-to-date: 4 December 2009.

Date	Event	Description
29 April 2011	Amended	Text regarding the success of blinding for the study by Waagen et al. (Waagen 1986) has been modified in the results section (under Risk of bias in included studies: Blinding) and in the discussion section where these results are discussed

HISTORY

Protocol first published: Issue 4, 2009

Review first published: Issue 2, 2011

CONTRIBUTIONS OF AUTHORS

Conception and design: SM Rubinstein, MW van Tulder, WJJ Assendelft,

Analysis and interpretation of the data: SM Rubinstein, MR de Boer, MW van Tulder

Drafting of the review: SM Rubinstein, MW van Tulder

Critical revision of the article for important intellectual content: All members

Final approval of the article: All members

Statistical Expertise: MR de Boer

Administrative, technical, or logistical support: SM Rubinstein, MR de Boer

Collection and assembly of data: SM Rubinstein, M van Middelkoop, MR de Boer, WJJ Assendelft (studies published before 2000).

DECLARATIONS OF INTEREST

None

SOURCES OF SUPPORT

Internal sources

- Faculty of Earth and Life Sciences, VU University, Amsterdam, The Netherlands, Not specified.

External sources

- Dutch Health Insurance Council (CVZ), Not specified.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Addition of follow-up measurement in the meta-analyses. Three months was added as a follow-up measurement in the meta-analyses because it was reported in many studies and we felt that it was important to include. Reactions to SMT are principally short-term; therefore, to exclude this measurement would have meant an important loss of valuable data.

Under *sub-group analysis and investigation of heterogeneity.* Originally, we wanted to investigate the effects of SMT by different sub-groups with low-back pain, that is, by subjects with radiating pain to the knee *versus* those with pain below the knee or those with clear neurological deficit; however, these data were not available.

NOTES

Since the previous publication in 2004, this review has been split into two: acute and chronic. In total, 26 RCTs were identified, 18 of which are new studies not previously identified, representing approximately two-thirds of the included studies.

INDEX TERMS

Medical Subject Headings (MeSH)

Chronic Disease; Low Back Pain [*therapy]; Manipulation, Spinal [*methods]; Randomized Controlled Trials as Topic

MeSH check words

Adult; Humans